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8. I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

DATE: April 03, 2025

Mina Ching

Mina Ching

EXHIBIT A

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LABEL: POTASSIUM PHOSPHATES- monobasic potassium phosphate and dibasic potassium phosphate injection

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DRUG LABEL INFORMATION

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HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use POTASSIUM PHOSPHATES INJECTION safely and effectively. See full prescribing information for POTASSIUM PHOSPHATES INJECTION.

POTASSIUM PHOSPHATES injection, for intravenous use
Initial U.S. Approval: 1983

INDICATIONS AND USAGE

POTASSIUM PHOSPHATES INJECTION is a phosphorus replacement product indicated as a source of phosphorus: (1)

- in intravenous fluids to correct hypophosphatemia in adults and pediatric patients 12 years of age and older when oral or enteral replacement is not possible, insufficient or contraindicated. (1.1)
- for parenteral nutrition in adults weighing at least 45 kg and pediatric patients 12 years of age and older weighing at least 40 kg when oral or enteral nutrition is not possible, insufficient or contraindicated. (1.2)
  - Limitations of Use: Safety has not been established for parenteral nutrition in adults weighing less than 45 kg or pediatric patients less than 12 years of age or weighing less than 40 kg due to the risk of aluminum toxicity. (1.2, 5.5, 8.4)

DOSAGE AND ADMINISTRATION

- Administer intravenously only after dilution or admixing in a larger volume of fluid. (2.1)
- POTASSIUM PHOSPHATES INJECTION provides phosphorus 3 mmol/mL (potassium 4.7 mEq/mL). (2.2, 2.4)
- Monitor serum phosphorus, potassium, calcium, and magnesium concentrations. (2.2, 2.4)
- See full prescribing information for instructions on preparation and administration. (2.1, 2.3)

Recommended Dosage for Correction of Hypophosphatemia in Intravenous Fluids: (2)

- POTASSIUM PHOSPHATES INJECTION is only for administration to a patient with a serum potassium concentration less than 4 mEq/dL; otherwise, use an alternative source of phosphate. (2.1)
- The dosage is dependent upon the individual needs of the patient, and the contribution of phosphorus and potassium from other sources. (2.2)
- See full prescribing information for recommendations on initial or single dosing, repeated dosing, concentration and infusion rate. (2.1, 2.2)

Recommended Dosage for Administration in Parenteral Nutrition: (2)

- Individualize the dosage based upon the patient's clinical condition, nutritional

requirements, and the contribution of oral or enteral phosphorus and potassium intake. (2.4)
- See full prescribing information for recommendations for daily and maximum dosage. (2.4)

DOSAGE FORMS AND STRENGTHS

Injection: phosphorus 45 mmol/15 mL (3 mmol/mL) and potassium 71 mEq/15 mL (4.7 mEq/mL) in a single-dose vial. (3)

CONTRAINDICATIONS

- hyperkalemia
- hyperphosphatemia (4)
- hypercalcemia or significant hypocalcemia (4)
- severe renal impairment (eGFR less than 30 mL/min/1.73m^2) and end stage renal disease (4)

WARNINGS AND PRECAUTIONS

- Serious Cardiac Adverse Reactions with Undiluted, Bolus, or Rapid Intravenous Administration: Administer only after dilution or admixing; do not exceed the recommended infusion rate. Continuous electrocardiographic (ECG) monitoring may be needed during infusion. (5.1)
- Pulmonary Embolism due to Pulmonary Vascular Precipitates: If signs of pulmonary distress occur, stop the infusion and initiate a medical evaluation. (5.2)
- Hyperkalemia: Increased risk in patients with renal impairment, severe adrenal insufficiency, or treated with drugs that increase potassium. Patients with cardiac disease may be more susceptible. Do not exceed the maximum daily amount of potassium or the recommended infusion rate. Continuous ECG monitoring may be needed during infusion. (5.3, 7.1)
- Hyperphosphatemia and Hypocalcemia: Monitor serum phosphorus and calcium concentrations during and following infusion. (5.4)
- Aluminum Toxicity: Increased risk in patients with renal impairment, including preterm infants. (5.5, 8.4).
- Hypomagnesemia: Reported in patients with hypercalcemia and diabetic ketoacidosis. Monitor serum magnesium concentrations during treatment. (5.6)
- Vein Damage and Thrombosis: Infuse concentrated or hypertonic solutions through a central catheter. (2.1, 2.3, 5.7)

ADVERSE REACTIONS

Adverse reactions are hyperkalemia, hyperphosphatemia, hypocalcemia and hypomagnesemia. (6)

To report SUSPECTED ADVERSE REACTIONS, contact CMP Pharma at 1-844-321-1443 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch. (6)

DRUG INTERACTIONS

Use of Other Medications that Increase Potassium: Avoid use in patients receiving such products. If use cannot be avoided, closely monitor serum potassium concentrations. (5.3, 7.1) (7)

See 17 for PATIENT COUNSELING INFORMATION.

Revised: 10/2019

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CLOSE

1 INDICATIONS AND USAGE

1.1 In Intravenous Fluids to Correct Hypophosphatemia

POTASSIUM PHOSPHATES INJECTION is indicated as a source of phosphorus in intravenous fluids to correct hypophosphatemia in adults and pediatric patients 12 years of age and older when oral or enteral replacement is not possible, insufficient or contraindicated.

1.2 For Parenteral Nutrition

POTASSIUM PHOSPHATES INJECTION is indicated as a source of phosphorus for parenteral nutrition in adults weighing at least 45 kg and pediatric patients 12 years of age and older weighing at least 40 kg when oral or enteral nutrition is not possible, insufficient or contraindicated.

Limitations of Use

Safety has not been established for parenteral nutrition in adults weighing less than 45 kg or pediatric patients less than 12 years of age or weighing less than 40 kg due to the risk of aluminum toxicity [*see Warnings and Precautions (5.5), Use in Specific Population (8.4)*].

CLOSE

2 DOSAGE AND ADMINISTRATION

2.1 Preparation and Administration in Intravenous Fluids to Correct Hypophosphatemia

Preparation

- POTASSIUM PHOSPHATES INJECTION is for intravenous infusion into a central or peripheral *vein only after dilution.*
- Using aseptic technique, withdraw the required dose from the vial and add to 100 mL to 250 mL of 0.9% Sodium Chloride Injection, USP (normal saline) or 5% Dextrose Injection, USP (D5W).
- The concentration of the diluted solution should take into consideration the amounts of phosphorus and potassium to be administered and is dependent upon whether administration will be through a peripheral or central venous catheter. The recommended maximum concentration is:
- phosphorus 6.4 mmol/100 mL (potassium 10 mEq/100 mL) for peripheral administration
- phosphorus 18 mmol/100 mL (potassium 28.2 mEq/100mL) for central administration
- Visually inspect the solution for particulate matter and discoloration before and after dilution and prior to administration. Do not administer unless solution is clear, and seal on the vial is intact.

Administration

- Check serum potassium and calcium concentrations prior to administration. Normalize the calcium before administering POTASSIUM PHOSPHATES INJECTION [*see Contraindications*

(4), Warnings and Precautions (5.3,5.4)].

- POTASSIUM PHOSPHATES INJECTION is only for administration to a patient with a serum potassium concentration less than 4 mEq/dL[*see Warnings and Precautions (5.3)*]. If the potassium concentration is 4 mEq/dL or more, use an alternative source of phosphate.
- Do not infuse with calcium-containing intravenous fluids [see *Warnings and Precautions (5.4)*].
- The rate of administration may be dependent on the patient and the specific institution policy [*see Dosage and Administration (2.2)*].

Storage and Stability

- For single use only. Discard used vial, including any unused contents.
- After dilution, the solution is stable for 48 hours under refrigeration at 2°C to 8°C (36°F to 46°F) or at room temperature from 20°C to 25°C (68°F to 77°F).

2.2 Dosage for Administration in Intravenous Fluids to Correct Hypophosphatemia

POTASSIUM PHOSPHATES INJECTION provides phosphorus 3 mmol/mL (potassium 4.7 mEq/mL).

The dosage is dependent upon the individual needs of the patient, and the contribution of phosphorus and potassium from other sources.

Initial or Single Dose

The phosphorus doses in Table 1 are general recommendations for an initial or single dose and are intended for most patients. Based upon clinical requirements, some patients may require a lower or higher dose. The maximum initial or single dose of phosphorus is 45 mmol (potassium 71 mEq) [*see Warnings and Precautions (5.1)*].

In patients with moderate renal impairment (eGFR ≥30 mL/min/1.73 m^2 to <60 mL/min/1.73 m^2), start at the low end of the dose range [*see Use in Specific Populations (8.6)*].

Monitor serum phosphorus, potassium, calcium and magnesium serum concentrations.

TABLE 1: Recommended Initial or Single Dose of POTASSIUM PHOSPHATES INJECTION in Intravenous Fluids to Correct Hypophosphatemia in Adults and Pediatric Patients 12 Years of Age and Older

Serum Phosphorus Concentration[a]	Phosphorus Dosage[b,c]	Corresponding Potassium Content
1.8 mg/dL to 2.4 mg/dL	0.16 mmol/kg to 0.31 mmol/kg	0.25 mEq/kg to 0.49 mEq/kg of potassium
1 mg/dL to 1.7 mg/dL	0.32 mmol/kg to 0.43 mmol/kg	0.5 mEq/kg to 0.68 mEq/kg of potassium
Less than 1 mg/dL	0.44 mmol/kg to 0.64 mmol/kg[c]	0.69 mEq/kg to 1 mEq/kg of potassium

[a] Serum phosphorus reported using 2.5 mg/dL as the lower end of the reference range for healthy adults. Serum phosphorus concentrations may vary depending on the assay used and the laboratory reference range.
[b] Weight is in terms of actual body weight. Limited information is available regarding dosing of patients significantly above ideal body weight; consider using an adjusted body weight for these patients.
[c] up to a maximum of phosphorus 45 mmol (potassium 71 mEq) as a single dose.

Concentration and Intravenous Infusion Rate

- The concentration of the diluted solution and the infusion rate is dependent upon whether administration will be through a peripheral or central venous catheter.

Peripheral administration:

- The maximum recommended concentration is phosphorus 6.4 mmol/100 mL (potassium10 mEq/100 mL).
- The maximum recommended infusion rate is approximately phosphorus 6.4 mmol/hour (potassium 10 mEq/hour).

Central administration:

- The maximum recommended concentration is phosphorus 18 mmol/100 mL (potassium 28.2 mEq/100 mL).
- The maximum recommended infusion rate is approximately phosphorus 15 mmol/hour (potassium 23.5 mEq/hour).
- Continuous electrocardiographic (ECG) monitoring and infusion through a central venous catheter is recommended for infusion rates of potassium higher than 10 mEq/hour in adults and 0.5 mEq/kg/hour in pediatric patients 12 years of age and older.

Repeated Dosing

Additional dose(s) following the initial dose may be needed in some patients. Prior to administration of additional doses, assess the patient clinically and obtain serum phosphorous, calcium and potassium

concentrations and adjust the dose accordingly.

2.3 Preparation and Administration in Parenteral Nutrition

- POTASSIUM PHOSPHATES INJECTION is for *intravenous infusion* into a peripheral or central vein *only after dilution and admixing.*
- POTASSIUM PHOSPHATES INJECTION is to be prepared only in a suitable work area such as a laminar flow hood (or an equivalent clean air compounding area). The key factor in the preparation is careful aseptic technique to avoid inadvertent touch contamination during mixing of solutions and addition of other nutrients.
- Transfer the required amount of POTASSIUM PHOSPHATES INJECTION to the parenteral nutrition solution following the admixture of amino acids, dextrose, electrolytes solutions, and prior to lipids (if added).
- Because additives may be incompatible, evaluate all additions to the parenteral nutrition container for compatibility and stability of the resulting preparation.
- Calcium and phosphate ratios must be considered. Excess addition of calcium and phosphate, especially in the form of mineral salts, may result in the formation of calcium-phosphate precipitates [*see Warnings and Precautions (5.2)*]. Calcium-phosphate stability in parenteral nutrition solutions is dependent upon the pH of the solution, temperature, and relative concentration of each ion. Discard if any precipitates are observed.
- Inspect the final parenteral solution containing POTASSIUM PHOSPHATES INJECTION to ensure that:
  - precipitates have not formed during mixing or addition of additives and inspect again before administration.
  - the emulsion has not separated, if lipids have been added. Separation of the emulsion can be visibly identified by a yellowish streaking or the accumulation of yellowish droplets in the admixed emulsion.
- The final parenteral nutrition solution is for intravenous infusion into a peripheral or central vein. The choice of a peripheral or central venous route should depend on the osmolarity of the final infusate. Solutions with osmolarity of 900 mOsm/L or greater must be infused through a central catheter [*see Warnings and Precautions (5.7)*].

Storage and Stability

- For single use only. Discard used vial, including any unused contents.
- Use parenteral nutrition solution promptly after mixing. Any storage of the admixture should be under refrigeration from 2°C to 8°C (36°F to 46°F) and limited to a brief period of time, no longer than 24 hours. After removal from refrigeration, bring to room temperature and use promptly and complete the infusion within 24 hours. Discard any remaining admixture.
- Protect the parenteral nutrition solution from light during storage.

2.4 Dosage for Administration in Parenteral Nutrition

POTASSIUM PHOSPHATES INJECTION provides phosphorus 3 mmol/mL (potassium 4.7 mEq/mL).

The recommended and maximum daily dosage in parenteral nutrition is shown in Table 2. Individualize the dosage based upon the patient's clinical condition, nutritional requirements, and the contribution of oral or enteral phosphorus and potassium intake. The amount of phosphorus that can be added to parenteral nutrition may be limited by the amount of calcium that is also added to the solution.

TABLE 2: Recommended Daily Dosage of POTASSIUM PHOSPHATES INJECTION for Parenteral Nutrition

Patient Population	Generally Recommended Phosphorus Daily Dosage[a] (Potassium Content)	Maximum Phosphorus Dosage (Potassium Content) Based Upon Aluminum Content[a]
Adults weighing at least 45 kg	20 mmol/day to 40 mmol/day[b] (potassium 31 mEq/day to 62.7 mEq/day)	45 mmol/day (potassium 71 mEq/day)
Pediatric patients 12 years of age and older weighing at least 40 kg		40 mmol/day (potassium 62.7 mEq/day)

[a] see Warnings and Precautions (5.5), Use in Specific Populations (8.4)
[b] In patients with moderate renal impairment (eGFR ≥30 mL/min/1.73 m^2 to <60 mL/min/1.73 m^2), start at the low end of the dosage range.

Monitoring

Monitor serum phosphorus, potassium, calcium and magnesium concentrations and adjust the dosage accordingly.

CLOSE

3 DOSAGE FORMS AND STRENGTHS

POTASSIUM PHOSPHATES INJECTION, USP: phosphorus 45 mmol/15 mL (3 mmol/mL) and potassium 71 mEq/15 mL (4.7 mEq/mL) as a clear and colorless solution in a single-dose vial.

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4 CONTRAINDICATIONS

POTASSIUM PHOSPHATES INJECTION is contraindicated in patients with:

- hyperkalemia [*see Warnings and Precautions (5.3)*]
- hyperphosphatemia [*see Warnings and Precautions (5.4)*]
- hypercalcemia or significant hypocalcemia [*see Warnings and Precautions (5.4)*]
- severe renal impairment (eGFR less than 30 mL/min/1.73m^2) and end stage renal disease [*see Warnings and Precautions (5.3)*]

CLOSE

5 WARNINGS AND PRECAUTIONS

5.1 Serious Cardiac Adverse Reactions with Undiluted, Bolus or Rapid Intravenous Administration
Intravenous administration of potassium phosphates to correct hypophosphatemia in single doses of phosphorus 50 mmol and greater and/or at rapid infusion rates (over 1 to 3 hours) in intravenous fluids has resulted in death, cardiac arrest, cardiac arrhythmia (including QT prolongation), hyperkalemia, hyperphosphatemia, and seizures [*see Overdosage (10)*]. In addition, inappropriate intravenous administration of undiluted or insufficiently diluted potassium phosphates as a rapid "IV push" has resulted in cardiac arrest, cardiac arrhythmias, hypotension, and death.

POTASSIUM PHOSPHATES INJECTION is for *intravenous infusion only after dilution or admixing.* The maximum initial or single dose of POTASSIUM PHOSPHATES INJECTION in intravenous fluids to correct hypophosphatemia is phosphorus 45 mmol (potassium 71 mEq). The recommended infusion rate is approximately phosphorus 6.4 mmol/hour (potassium 10 mEq/hour). Continuous electrocardiographic (ECG) monitoring is recommended for higher infusion rates [*see Dosage and Administration (2.1, 2.2)*].

5.2 Pulmonary Embolism due to Pulmonary Vascular Precipitates
Pulmonary vascular emboli and pulmonary distress related to precipitates in the pulmonary vasculature have been described in patients receiving admixed products containing calcium and phosphates or parenteral nutrition. The cause of precipitate formation has not been determined in all cases; however, in some fatal cases, pulmonary emboli occurred as a result of calcium phosphate precipitates. Precipitation has occurred following passage through an in-line filter; *in vivo* precipitate formation may also have occurred. If signs of pulmonary distress occur, stop the parenteral nutrition infusion and initiate a medical evaluation. In addition to inspection of the solution [*see Dosage and Administration (2.1, 2.3)*], the infusion set and catheter should also periodically be checked for precipitates.

5.3 Hyperkalemia
POTASSIUM PHOSPHATES INJECTION may increase the risk of hyperkalemia, including life-threatening cardiac events, especially when administered in excessive doses, undiluted or by rapid intravenous infusion [*see Warnings and Precautions (5.1)*]. Patients with severe renal impairment and end stage renal disease are at increased risk of developing life-threatening hyperkalemia, when administered intravenous potassium [*see Contraindications (4)*]. Other patients at increased risk of hyperkalemia include those with severe adrenal insufficiency or treated concurrently with other drugs that cause or increase the risk of hyperkalemia [*see Drug Interactions (7.1)*]. Patients with cardiac disease may be more susceptible to the effects of hyperkalemia.

Consider the amount of potassium from all sources when determining the dose of POTASSIUM PHOSPHATES INJECTION and do not exceed the maximum age-appropriate recommended daily amount of potassium. In patients with moderate renal impairment (eGFR ≥30 mL/min/1.73 m^2 to <60 mL/min/1.73 m^2), start at the low end of the dose range and monitor serum potassium, phosphorus, calcium, and magnesium concentrations [*see Dosage and Administration (2.2, 2.4), Use in Specific Populations (8.6)*].

When administering POTASSIUM PHOSPHATES INJECTION in intravenous fluids to correct hypophosphatemia, check the serum potassium concentration prior to administration. If the potassium concentration is 4 mEq/dL or more, do not administer POTASSIUM PHOSPHATES INJECTION and use an alternative source of phosphate [*see Dosage and Administration (2.1)*]. The maximum initial or single dose of POTASSIUM PHOSPHATES INJECTION in intravenous fluids to correct hypophosphatemia is phosphorus 45 mmol (potassium 71 mEq). The recommended infusion rate of potassium is 10 mEq/hour. Continuous electrocardiographic (ECG) monitoring is recommended for higher infusion rates of potassium [*see Dosage and Administration (2.2)*].

5.4 Hyperphosphatemia and Hypocalcemia
Hyperphosphatemia can occur with intravenous administration of potassium phosphates, especially in patients with renal impairment.
Hyperphosphatemia can cause the formation of insoluble calcium phosphorus products with consequent hypocalcemia, neurological irritability with tetany, nephrocalcinosis with acute kidney injury and more rarely, cardiac irritability with arrhythmias.

Obtain serum calcium concentrations prior to administration and normalize the calcium before administering POTASSIUM PHOSPHATES INJECTION. POTASSIUM PHOSPHATES INJECTION is contraindicated in patients with hyperphosphatemia and/or hypercalcemia [*see Contraindications (4)*].

Monitor serum phosphorus and calcium concentrations during treatment with POTASSIUM PHOSPHATES INJECTION [*see Dosage and Administration (2.2)*].

5.5 Aluminum Toxicity

POTASSIUM PHOSHATES INJECTION contains aluminum that may be toxic.

Aluminum may reach toxic levels with prolonged parenteral administration in patients with renal impairment. Preterm infants are particularly at risk for aluminum toxicity because their kidneys are immature, and they require large amounts of calcium and phosphate solutions, which also contain aluminum.

Patients with renal impairment, including preterm infants, who receive greater than 4 to 5 mcg/kg/day of parenteral aluminum can accumulate aluminum to levels associated with central nervous system and bone toxicity. Tissue loading may occur at even lower rates of administration.

Exposure to aluminum from POTASSIUM PHOSPHATES INJECTION is not more than 4.9 mcg/kg/day when:

- adults weighing at least 45 kg are administered the recommended maximum dosage of phosphorus (45 mmol/day) for parenteral nutrition.
- pediatric patients 12 years of age and older weighing at least 40 kg are administered the recommended maximum dosage of phosphorus (40 mmol/day) for parenteral nutrition [*see Dosage and Administrations (2.4), Description (11)*].

When prescribing POTASSIUM PHOSPHATES INJECTION for use in parenteral nutrition solutions containing other small volume parenteral products, the total daily patient exposure to aluminium from the admixture should be considered and maintained at no more than 5 mcg/kg/day [*see Use in Specific Populations (8.4)*].

POTASSIUM PHOSPHATES INJECTION for parenteral nutrition is not recommended in adults weighing less than 45 kg or pediatric patients less than 12 years of age or weighing less than 40 kg due to the risks of aluminum toxicity [*see Indications and Usage (1.2)*].

5.6 Hypomagnesemia

Intravenous infusion of phosphate has been reported to cause a decrease in serum magnesium (and calcium) concentrations when administered to patients with hypercalcemia and diabetic ketoacidosis. Monitor serum magnesium concentrations during treatment.

5.7 Vein Damage and Thrombosis

POTASSIUM PHOSPHATES INJECTION must be diluted and administered in intravenous fluids or used as an admixture in parenteral nutrition. It is not for direct intravenous infusion. The infusion of hypertonic solutions into a peripheral vein may result in vein irritation, vein damage, and/or thrombosis. The primary complication of peripheral administration is venous thrombophlebitis, which manifests as pain, erythema, tenderness or a palpable cord. Remove the catheter as soon as possible and initiate appropriate medical treatment if thrombophlebitis develops.

When administered peripherally in intravenous fluids to correct hypophosphatemia, a generally recommended maximum concentration is phosphorus 6.4 mmol/100 mL (potassium 10 mEq/100 mL) [*see Dosage and Administration (2.1)*]

Parenteral nutrition solutions with an osmolarity of 900 mOsm/L or greater must be infused through a central catheter [*see Dosage and Administration (2.3)*].

5.8 Laboratory Monitoring

Monitor serum phosphorus, potassium, calcium and magnesium concentrations during treatment [*see Dosage and Administration (2.2, 2.4)*].

CLOSE

6 ADVERSE REACTIONS

The following clinically significant adverse reactions are described elsewhere in the labeling:

- Aluminum Toxicity [*see Warnings and Precautions (5.5)*]
- Hypomagnesemia [*see Warnings and Precautions (5.6)*]
- Vein Damage and Thrombosis [*see Warnings and Precautions (5.7)*]

The following adverse reactions in Table 3 have been reported in clinical studies or postmarketing reports in patients receiving intravenously administered potassium phosphates. Because some of these reactions were reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

TABLE 3: Adverse Reactions Reported in Clinical Studies or Postmarketing Reports with Intravenous Potassium Phosphates

System Organ Class	Adverse Reactions
Metabolism and Nutrition Disorders	pulmonary embolism due to pulmonary vascular precipitates [*see Warnings and Precautions (5.2)*], hyperkalemia [*see Warnings and Precautions (5.3)*], hyperphosphatemia [*see Warnings and Precautions (5.4)*], hypocalcemia [*see Warnings and Precautions (5.5)*], hypovolemia, and osmotic diuresis

	Warnings and Precautions (5.5)], hypokalemia, and osmotic diuresis
Cardiac Disorders	hypotension, arrhythmia, heart block, cardiac arrest, bradycardia, chest pain, ECG changes [*see Warnings and Precautions (5.1)*], and edema
Respiratory, Thoracic, and Mediastinal Disorders	dyspnea [*see Warnings and Precautions (5.2)*]
Renal and Urinary Disorders	acute phosphate nephropathy (i.e., nephrocalcinosis with acute kidney injury), decreased urine output, and transition to chronic kidney disease [*see Warnings and Precautions (5.4)*]
Gastrointestinal Disorders	diarrhea, stomach pain
Musculoskeletal and Connective Tissue Disorders	weakness
Nervous System Disorders	confusion, lethargy, paralysis, paresthesia

CLOSE

7 DRUG INTERACTIONS

7.1 Other Products that Increase Serum Potassium

Administration of POTASSIUM PHOSPHATES INJECTION to patients treated concurrently or recently with products that increase serum potassium (e.g., potassium-sparing diuretics, ACE inhibitors, angiotensin II receptor antagonists, digoxin, or the immunosuppressants tacrolimus and cyclosporine) increases the risk of severe and potentially fatal hyperkalemia, in particular in the presence of other risk factors for hyperkalemia [*see Warnings and Precautions (5.2)*]. Avoid use of POTASSIUM PHOSPHATES INJECTION in patients receiving such products. If use cannot be avoided, closely monitor serum potassium concentrations [*see Dosage and Administration (2.2, 2.3)*].

CLOSE

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

Administration of the approved recommended dose of POTASSIUM PHOSPHATES INJECTION is not expected to cause major birth defects, miscarriage, or adverse maternal or fetal outcomes. Animal reproduction studies have not been conducted with intravenous potassium phosphates.

The estimated background risk of major birth defects and miscarriage for the indicated populations is unknown. All pregnancies have a background risk of birth defect, loss, or other adverse outcomes. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2 to 4% and 15 to 20%, respectively.

Clinical Considerations

Disease-associated Maternal and/or Embryo-Fetal Risk

Phosphorus is an essential mineral element. Parenteral supplementation with potassium phosphates should be considered if a pregnant woman's requirements cannot be fulfilled by oral or enteral intake.

8.2 Lactation

Risk Summary

Phosphorus and potassium are present in human milk. Administration of the approved recommended dose of POTASSIUM PHOSPHATES INJECTION is not expected to cause harm to a breastfed infant. There is no information on the effects of potassium phosphates on milk production. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for POTASSIUM PHOSPHATES INJECTION and any potential adverse effects on the breastfed infant from POTASSIUM PHOSPHATES INJECTION or from the underlying maternal condition.

8.4 Pediatric Use

Safety and effectiveness of POTASSIUM PHOSPHATES INJECTION have been established in:

- pediatric patients 12 years and older as a source of phosphorus in intravenous fluids to correct hypophosphatemia when oral or enteral replacement is not possible, insufficient, or contraindicated.
- pediatric patients 12 years and older weighing at least 40 kg as a source of phosphorus for parenteral nutrition when oral or enteral nutrition is not possible, insufficient, or contraindicated.

The safety of POTASSIUM PHOSPHATES INJECTION for parenteral nutrition has not been established in pediatric patients less than 12 years of age or in adolescents weighing less than 40 kg due to the risk of aluminum toxicity [*see Indications and Usage (1.2), Warnings and Precautions (5.5)*].

8.5 Geriatric Use

In general, dose selection of POTASSIUM PHOSPHATES INJECTION for an elderly patient should be cautious, starting at the low end of the dosing range because of the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy. It may be useful to monitor renal function during treatment [*see Use in Specific Populations (8.6)*].

8.6 Renal Impairment

Potassium and phosphorus are known to be substantially excreted by the kidney and the risk of adverse reactions to POTASSIUM PHOSPHATES INJECTION may be greater in patients with impaired renal function [*see Warnings and Precautions (5.3, 5.4, 5.5)*].

POTASSIUM PHOSPHATES INJECTION is contraindicated due to the risk of hyperkalemia in patients with severe renal impairment (eGFR less than 30 mL/min/1.73 m^2) or end stage renal disease [*see Contraindications (4)*].

In patients with moderate renal impairment (eGFR ⩾ 30 mL/min/1.73 m^2 to < 60 mL/min/1.73 m^2), start at the low end of the dosage range and monitor serum potassium, phosphorus, calcium, and magnesium concentrations [*see Dosage and Administration (2.2, 2.4)*].

CLOSE

10 OVERDOSAGE

Hyperphosphatemia

Administration of excessive doses of intravenous potassium phosphates in intravenous fluids as a single dose ranging from approximately 50 to 270 mmol and/or at rapid infusion rates (over 1 to 3 hours) has resulted in death, cardiac arrest, cardiac arrhythmia (including QT prolongation), hyperkalemia, hyperphosphatemia, seizures, and tetany.

Hyperphosphatemia is particularly a risk in patients with renal failure. Hyperphosphatemia leads in turn to hypocalcemia, which may be severe, and to ectopic calcification, particularly in patients with initial hypercalcemia. Tissue calcification may cause hypotension and organ damage and result in acute renal failure.

Hyperkalemia

Excessive administration of phosphates given as potassium salts may also cause hyperkalemia. Manifestations of hyperkalemia include:

- Disturbances in cardiac conduction and arrhythmias, including bradycardia, heart block, asystole, ventricular tachycardia, ventricular fibrillation
- Hypotension
- Muscle weakness including paresthesia, muscular and respiratory paralysis

Management

In the event of overdosage, discontinue infusions containing potassium phosphates immediately and institute general supportive measures, including ECG monitoring, laboratory monitoring, and correction of serum electrolyte concentrations, especially potassium, phosphorus, calcium, and magnesium.

CLOSE

11 DESCRIPTION

POTASSIUM PHOSPHATES INJECTION, USP, is a phosphorus replacement product containing phosphorus 45 mmol/15 mL (3 mmol/mL) and potassium 71 mEq/15 mL (4.7 mEq/mL). It is a sterile, nonpyrogenic, concentrated solution containing a mixture of monobasic potassium phosphate and dibasic potassium phosphate in water for injection. It is supplied as a 15 mL partial fill single-dose glass vial.

Monobasic Potassium Phosphate is chemically designated KH_2PO_4, molecular weight 136.09, white, odorless crystals or granules freely soluble in water.

Dibasic Potassium Phosphate is chemically designated K_2HPO_4, molecular weight 174.18, colorless or white granular salt freely soluble in water.

The solution is administered after dilution or admixing by the intravenous route.

Each mL contains 175 mg of monobasic potassium phosphate and 300 mg of dibasic potassium phosphate.

Each mL contains 3 mmol phosphorus (equivalent to 93 mg phosphorous) and 4.7 mEq potassium (equivalent to 184 mg of potassium). Note: 1 mmol of phosphorus is equal to 1 mmol phosphate. The pH is 6.5 to 7.5.

This product contains no more than 15,000 mcg/L of aluminum [*see Warnings and Precautions (5.5)*].

The osmolar concentration is 7.7 mOsmol/mL (calc).

CLOSE

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

Phosphorus in the form of organic and inorganic phosphate has a variety of biochemical functions in all

organs and tissues, including critical roles in nucleic acid structure, energy storage and transfer, cell signaling, cell membrane composition and structure, acid-base balance, mineral homeostasis and bone mineralization.

12.3 Pharmacokinetics

Distribution

Approximately 85% of serum phosphates is free and ultra-filterable and 15% is protein-bound.

Elimination

Intravenously infused phosphates not taken up by the tissues are excreted almost entirely in the urine. Serum phosphorus is believed to be filterable by the renal glomeruli and the major portion of filtered phosphorus (greater than 80%) is actively reabsorbed by the tubules.

CLOSE

16 HOW SUPPLIED/STORAGE AND HANDLING

POTASSIUM PHOSPHATES INJECTION, USP: phosphorus 45 mmol/15 mL (3 mmol/mL) and potassium 71 mEq/15 mL (4.7 mEq/mL) as a clear and colorless solution supplied in a 15 mL single-dose glass vial (NDC 46287-024-15) in a ten count carton (NDC 46287-024-10).

Store at 2°C to 8°C (36°F to 46°F). Do not freeze.

For storage of admixed solution *see Dosage and Administration 2.2, 2.4.*

CLOSE

17 PATIENT COUNSELING INFORMATION

Inform patients, caregivers or home healthcare providers of the following risks of POTASSIUM PHOSPHATES INJECTION:

- Serious Cardiac Adverse Reactions with Undiluted, Bolus or Rapid Intravenous Administration [*see Warnings and Precautions (5.1)*]
- Pulmonary Embolism due to Pulmonary Vascular Precipitates [*see Warnings and Precautions (5.2)*]
- Hyperkalemia [*see Warnings and Precautions (5.3)*]
- Hyperphosphatemia and Hypocalcemia [*see Warnings and Precautions (5.4)*]
- Aluminum toxicity [*see Warnings and Precautions (5.5)*]
- Hypomagnesemia [*see Warnings and Precautions (5.6)*]
- Vein Damage and Thrombosis [*see Warnings and Precautions (5.7)*]

CLOSE

SPL UNCLASSIFIED SECTION

Distributed by:
CMP Pharma Inc.
8026 US Highway 264A, Farmville, NC 27828

CLOSE

PRINCIPAL DISPLAY PANEL

PRINCIPAL DISPLAY PANEL - 10 x 15 mL Vial Carton

NDC 46287-024-10
Rx Only

10 x 15 mL

Single-Dose Vial - Discard Unused Portion

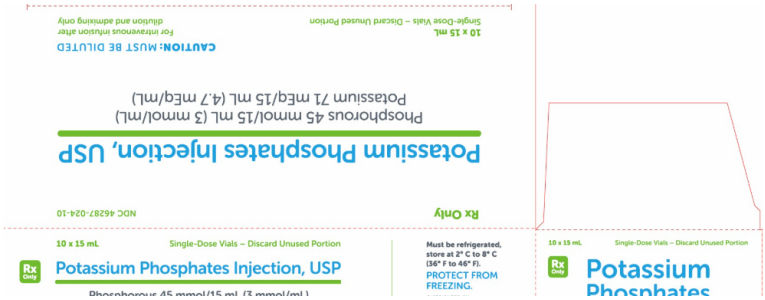
Potassium Phosphates Injection, USP

Phophorus 45 mmol/15 mL (3 mmol/mL)

Potassium 71 mEq/15 mL (4.7 mEq/mL)

Caution: MUST BE DILUTED

For intravenous infusion after dilution and admixing only





CLOSE

INGREDIENTS AND APPEARANCE

POTASSIUM PHOSPHATES
monobasic potassium phosphate and dibasic potassium phosphate injection

PRODUCT INFORMATION			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:46287-024
Route of Administration	INTRAVENOUS		

ACTIVE INGREDIENT/ACTIVE MOIETY		
Ingredient Name	**Basis of Strength**	**Strength**
POTASSIUM PHOSPHATE, MONOBASIC (UNII: 4J9FJ0HL51) (PHOSPHATE ION - UNII:NK08V8K8HR)	POTASSIUM PHOSPHATE, MONOBASIC	175 mg in 1 mL
POTASSIUM PHOSPHATE, DIBASIC (UNII: CI71S98N1Z) (PHOSPHATE ION - UNII:NK08V8K8HR)	POTASSIUM PHOSPHATE, DIBASIC	300 mg in 1 mL

INACTIVE INGREDIENTS	
Ingredient Name	**Strength**
WATER (UNII: 059QF0KO0R)	

PACKAGING				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:46287-024-15	1 in 1 CARTON	09/19/2019	
1		15 mL in 1 VIAL, SINGLE-DOSE; Type 0: Not a Combination Product		
2	NDC:46287-024-10	10 in 1 CARTON	09/19/2019	
2		15 mL in 1 VIAL, SINGLE-DOSE; Type 0: Not a Combination Product		

MARKETING INFORMATION			
Marketing Category	**Application Number or Monograph Citation**	**Marketing Start Date**	**Marketing End Date**
NDA	NDA212121	09/19/2019	

LABELER - CMP PHARMA, INC. (005224175)

CLOSE

CLOSE ALL SECTIONS

FIND ADDITIONAL RESOURCES (also available in the left menu)

SAFETY

Report Adverse Events, FDA Safety Recalls, Presence in Breast Milk

RELATED RESOURCES

Medline Plus, Clinical Trials, PubMed, Biochemical Data Summary

MORE INFO ON THIS DRUG

View Label Archives, RxNorm, Get Label RSS Feed, View NDC Code(s) NEW!

NIH NLM

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National Institutes of Health | U.S. National Library of Medicine | Health & Human Services

https://web.archive.org/web/20191213002035/https://www.fda.gov/drugs/drug-approvals-and-databases/additionsdeletions-prescription-and-otc-drug-product-lists

INTERNET ARCHIVE Wayback Machine https://www.fda.gov/drugs/drug-approvals-and-databases/additionsdeletions-prescription-and-otc-drug-product-lists Go SEP DEC 13 SEP 106 capt 12 Jun 2019 2018 2019 2020 About this capture

An official website of the United States government Here's how you know

Additions/Deletions for Prescription and OTC Drug Product Lists

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Drug Approvals and Databases

Drug Trials Snapshots

Resources for Information on Approved Drugs

Orange Book Home Page

Content current as of:
11/15/2019

This document is not a cumulative list of approved Prescription and OTC Drug Products but a list of the new additions and new deletions to the Prescription and OTC Drug Product Lists for a specific month. This information must be used in conjunction with the most current Cumulative Supplement and Orange Book. Additions and deletions are identified in this document by the symbols >ADD> and >DLT>, respectively. Products that have never been marketed, have been discontinued from marketing or that have had their approvals withdrawn for other than safety or efficacy reasons, will be flagged in this Cumulative Supplement with the "@" symbol to designate their non-marketed status. All products having a "@" symbol in the 12th Cumulative Supplement of the current Edition List will then be added to the "Discontinued Drug Product List" of the following Edition.

- **>ADD>** or **>A>** indicates **Addition**
- **>DLT>** or **>D>** indicates **Deletion**
- **@** indicates **drugs that have been discontinued from marketing or that have had their approvals withdrawn for other than safety or efficacy reasons**

2019 Additions and Deletions to Drug Product List

- January 2019: Additions and Deletions to the Drug Product List (PDF - 186KB)
- February 2019: Additions and Deletions to the Drug Product List (PDF - 257KB)
- March 2019: Additions and Deletions to the Drug Product List (PDF - 221KB)
- April 2019: Additions and Deletions to the Drug Product List (PDF - 174KB)
- May 2019: Additions and Deletions to the Drug Product List (PDF - 202KB)
- June 2019: Additions and Deletions to the Drug Product List (PDF - 243KB)
- July 2019: Additions and Deletions to the Drug Product List (PDF - 182KB)
- August 2019: Additions and Deletions to the Drug Product List (PDF - 182KB)
- September 2019: Additions and Deletions to the Drug Product List (PDF - 205KB)
- October 2019: Additions and Deletions to the Drug Product List (PDF - 222KB)

2018 Additions and Deletions to Drug Product List

- January 2018: Additions and Deletions to the Drug Product List (PDF - 186KB)
- February 2018: Additions and Deletions to the Drug Product List (PDF - 123KB)
- March 2018: Additions and Deletions to the Drug Product List (PDF - 198KB)
- April 2018: Additions and Deletions to the Drug Product List (PDF - 200KB)
- May 2018: Additions and Deletions to the Drug Product List (PDF - 200KB)

- May 2018: Additions and Deletions to the Drug Product List (PDF - 200KB)
- June 2018: Additions and Deletions to the Drug Product List (PDF - 181 KB)
- July 2018: Additions and Deletions to the Drug Product List (PDF - 170 KB)
- August 2018: Additions and Deletions to the Drug Product List (PDF - 189 KB)
- September 2018: Additions and Deletions to the Drug Product List (PDF - 189 KB)
- October 2018: Additions and Deletions to the Drug Product List (PDF - 193KB)
- November 2018: Additions and Deletions to the Drug Product List (PDF - 174KB)
- December 2018: Additions and Deletions to the Drug Product List (PDF - 151KB)

2017 Additions and Deletions to Drug Product List

- January 2017: Additions and Deletions to the Drug Product List
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2015 Additions and Deletions to Drug Product List

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2008 Additions and Deletions to Drug Product List

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EXHIBIT B

https://web.archive.org/web/20230616122345/https://www.sealedair.com/content/dam/medical-packaging/primary-medical-films/m312-spec-sheet.pdf

Sealed Air®

NEXCEL®
BRAND PRIMARY MEDICAL FILMS

PRODUCT DATA SHEET

M312 Film

CONSTRUCTION - Clear, 5-layer, polyolefin based coextrusion; electronically crosslinked

Properties	Test Method	Units	Data
Standard Thickness	ASTM D-6988	µm	190
Tensile Strength L	ASTM D-882	kg/cm^2	210
Tensile Strength T	ASTM D-882	kg/cm^2	287
Elongation @ Break L	ASTM D-882	%	520
Elongation @ Break T	ASTM D-882	%	655
Modulus of Elasticity L	ASTM D-882	kg/cm^2	840
Modulus of Elasticity T	ASTM D-882	kg/cm^2	770
Haze	ASTM D-1003 (A)	%	5
Total Light Transmission	ASTM D-1003 (A)	%	94
MVTR (at 38°C, 100% RH, BAR)	ASTM F-1249	g/m^2 X 24h	5
Grammage	ASTM D-646-96	g/m^2	176
Roll Width*		mm	120-450
Roll Length		M	500
Core Diameter (ID)		mm	153.8

*Widths outside this range may be available upon request.

GLOBAL SYSTEMS & SUPPORT

With over 100 sales, manufacturing, and research/development facilities world wide, Sealed Air has created a global network that ensures our people and our customers have access to the finest technology and support services available in the world. Built on a foundation of innovative thinking and a commitment to offering our customers a total systems approach to their business wherever they may be, Sealed Air is uniquely positioned to solve the most demanding packaging challenges with the most innovative packaging solutions available.

Note: These are typical values for Nexcel® M312 Materials. They are not intended for use as limiting specifications.
All statements or recommendations are based on data and knowledge considered to be true and accurate at the time of printing but should be verified by the user. Since the conditions of use are beyond our control we do not warrant the completeness or suitability for any intended purpose of any statement or recommendation, or the results to be obtained. Please read all statements or recommendations in conjunction with our conditions of sale including those limiting warranties and remedies which apply to all goods and services supplied by us. National or local legal requirements relating to health & safety at work and the protection of the environment shall be applicable in all cases.

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Date: 10/2021

Sealed Air®

NEXCEL®
BRAND PRIMARY MEDICAL FILMS

PRODUCT DATA SHEET

M312 Film

DESCRIPTION/INTENDED USE

The standard in advanced films for medical and pharmaceutical solutions.

Nexcel® M312 was specifically developed to be a superior performing primary packaging film for terminally sterilized medical and pharmaceutical solutions. Nexcel® M312 is designed to be chemically inert and have extremely low levels of extractables with a wide range of solutions - even under the demanding conditions of 121˚C autoclave sterilization. It is designed for demanding packaging applications such as saline, dextrose, dialysate solutions, irrigation solutions, parenteral drugs, and nutritional products, as well as a wide variety of non-sterilized products.

The film combines the following key benefits:

- WIDER SEALING WINDOW FOR IMPROVED MACHINABILITY AND EASE OF HANDLING
- ROBUST FILM STRUCTURE RESULTS IN FEWER LEAKERS DURING PRODUCTION AND DISTRIBUTION
- OPTIMISED BARRIER PROPERTIES PRESERVE DRUG EFFICACY
- EXTREMELY LOW EXTRACTABLES FOR BROADER DRUG COMPATIBILITY AND EFFICACY
- EXCELLENT LOW TEMPERATURE ABUSE RESISTANCE
- EXCELLENT CLARITY
- HEAT SEALABLE
- PVC AND PHTHALATE FREE
- STERILIZABLE AT 121˚C
- MEETS USP, EP, JP REQUIREMENTS, INCLUDING USP CLASS VI
- US DMF NO. 9705

For more information or to contact Sealed Air about M312, please visit

WWW.SEALEDAIR.COM

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Date: 10/2021

https://web.archive.org/web/20191215034819/https://www.fda.gov/media/131880/download

Prescription and Over-the-Counter Drug Product List
39TH EDITION
Cumulative Supplement Number 09 : September 2019
ADDITIONS/DELETIONS FOR PRESCRIPTION DRUG PRODUCT LIST

ABIRATERONE ACETATE
TABLET;ORAL
ABIRATERONE ACETATE

>A>	AB	GLENMARK PHARMS	250MG	A209227	001	Oct 16, 2019	Sep	NEWA
>A>	AB	QILU PHARM CO LTD	250MG	A212462	001	Sep 27, 2019	Sep	NEWA

ACETAMINOPHEN; BUTALBITAL
TABLET;ORAL
ALLZITAL

>D>		LARKEN LABS INC	325MG;25MG	A203484	001	Dec 04, 2015	Sep	CHRS
>A>		!	325MG;25MG	A203484	001	Dec 04, 2015	Sep	CHRS

ACETAMINOPHEN; CODEINE PHOSPHATE
TABLET;ORAL
ACETAMINOPHEN AND CODEINE PHOSPHATE

>A>	AA	EYWA	300MG;15MG	A211610	001	Jun 27, 2019	Sep	CAHN
>A>	AA		300MG;30MG	A211610	002	Jun 27, 2019	Sep	CAHN
>A>	AA		300MG;60MG	A211610	003	Jun 27, 2019	Sep	CAHN
>D>	AA	WES PHARMA INC	300MG;15MG	A211610	001	Jun 27, 2019	Sep	CAHN
>D>	AA		300MG;30MG	A211610	002	Jun 27, 2019	Sep	CAHN
>D>	AA		300MG;60MG	A211610	003	Jun 27, 2019	Sep	CAHN

ACETAMINOPHEN; HYDROCODONE BITARTRATE
TABLET;ORAL
HYDROCODONE BITARTRATE AND ACETAMINOPHEN

>D>	AA	LANNETT CO INC	300MG;5MG	A207171	001	Jun 20, 2017	Sep	DISC
>A>		@	300MG;5MG	A207171	001	Jun 20, 2017	Sep	DISC
>D>	AA		300MG;7.5MG	A207171	002	Jun 20, 2017	Sep	DISC
>A>		@	300MG;7.5MG	A207171	002	Jun 20, 2017	Sep	DISC
>D>	AA		300MG;10MG	A207171	003	Jun 20, 2017	Sep	DISC
>A>		@	300MG;10MG	A207171	003	Jun 20, 2017	Sep	DISC
>D>	AA		325MG;5MG	A207172	001	Jun 22, 2017	Sep	DISC
>A>		@	325MG;5MG	A207172	001	Jun 22, 2017	Sep	DISC
>D>	AA		325MG;7.5MG	A207172	002	Jun 22, 2017	Sep	DISC
>A>		@	325MG;7.5MG	A207172	002	Jun 22, 2017	Sep	DISC
>D>	AA		325MG;10MG	A207172	003	Jun 22, 2017	Sep	DISC
>A>		@	325MG;10MG	A207172	003	Jun 22, 2017	Sep	DISC

ACETAMINOPHEN; OXYCODONE HYDROCHLORIDE
TABLET;ORAL
OXYCODONE AND ACETAMINOPHEN

>A>	AA	ANDA REPOSITORY	325MG;5MG	A207834	001	Aug 15, 2019	Sep	CAHN
>A>	AA		325MG;7.5MG	A207834	002	Aug 15, 2019	Sep	CAHN
>A>	AA		325MG;10MG	A207834	003	Aug 15, 2019	Sep	CAHN
>D>	AA	HALO PHARM CANADA	325MG;5MG	A207834	001	Aug 15, 2019	Sep	CAHN
>D>	AA		325MG;7.5MG	A207834	002	Aug 15, 2019	Sep	CAHN
>D>	AA		325MG;10MG	A207834	003	Aug 15, 2019	Sep	CAHN

ACETIC ACID, GLACIAL
SOLUTION/DROPS;OTIC
ACETIC ACID

>A>	AT	MLV	2%	A040607	001	Feb 24, 2005	Sep	CAHN
>D>	AT	SAPTALIS PHARMS	2%	A040607	001	Feb 24, 2005	Sep	CAHN

ACYCLOVIR
TABLET;ORAL
ACYCLOVIR

>A>	AB	SQUARE PHARMS LTD	400MG	A209366	001	Oct 07, 2019	Sep	NEWA
>A>	AB		800MG	A209366	002	Oct 07, 2019	Sep	NEWA

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ADDITIONS/DELETIONS FOR PRESCRIPTION DRUG PRODUCT LIST

		ALBUTEROL SULFATE							
		TABLET;ORAL							
		ALBUTEROL SULFATE							
>D>	AB	AIZANT	EQ 2MG BASE	A210948	001	Mar 15, 2019	Sep	CAHN	
>D>	AB		EQ 4MG BASE	A210948	002	Mar 15, 2019	Sep	CAHN	
>A>	AB	ARISE	EQ 2MG BASE	A210948	001	Mar 15, 2019	Sep	CAHN	
>A>	AB		EQ 4MG BASE	A210948	002	Mar 15, 2019	Sep	CAHN	
		ALENDRONATE SODIUM							
		TABLET, EFFERVESCENT;ORAL							
		BINOSTO							
>A>		+! ASCEND THERAPS US	EQ 70MG BASE	N202344	001	Mar 12, 2012	Sep	CAHN	
>D>		+! MISSION PHARMA	EQ 70MG BASE	N202344	001	Mar 12, 2012	Sep	CAHN	
		ALFUZOSIN HYDROCHLORIDE							
		TABLET, EXTENDED RELEASE;ORAL							
		ALFUZOSIN HYDROCHLORIDE							
>D>	AB	HERITAGE PHARMA	10MG	A079056	001	Jul 18, 2011	Sep	DISC	
>A>		@	10MG	A079056	001	Jul 18, 2011	Sep	DISC	
		ALMOTRIPTAN MALATE							
		TABLET;ORAL							
		ALMOTRIPTAN MALATE							
>D>	AB	AJANTA PHARMA LTD	EQ 12.5MG BASE	A205523	002	Mar 03, 2016	Sep	CHRS	
>A>	AB	!	EQ 12.5MG BASE	A205523	002	Mar 03, 2016	Sep	CHRS	
>D>		AXERT							
>D>	AB	+ JANSSEN PHARMS	EQ 6.25MG BASE	N021001	001	May 07, 2001	Sep	DISC	
>A>		+ @	EQ 6.25MG BASE	N021001	001	May 07, 2001	Sep	DISC	
>D>	AB	+!	EQ 12.5MG BASE	N021001	002	May 07, 2001	Sep	DISC	
>A>		+ @	EQ 12.5MG BASE	N021001	002	May 07, 2001	Sep	DISC	
		ALOSETRON HYDROCHLORIDE							
		TABLET;ORAL							
		ALOSETRON HYDROCHLORIDE							
>A>	AB	EYWA PHARMA	EQ 0.5MG BASE	A211621	001	Sep 16, 2019	Sep	NEWA	
>A>	AB		EQ 1MG BASE	A211621	002	Sep 16, 2019	Sep	NEWA	
		ALPHA-TOCOPHEROL ACETATE; ASCORBIC ACID; BIOTIN; CHOLECALCIFEROL; CYANOCOBALAMIN; DEXPANTHENOL; FOLIC ACID; NIACINAMIDE; PYRIDOXINE HYDROCHLORIDE; RIBOFLAVIN 5'-PHOSPHATE SODIUM; THIAMINE HYDROCHLORIDE; VITAMIN A PALMITATE; VITAMIN K							
		SOLUTION;INTRAVENOUS							
		INFUVITE ADULT							
>A>		+! SANDOZ CANADA INC	2 IU/ML;40MG/ML;12MCG/ML;40 IU/ML;1MCG/ML;3MG/ML;120MCG/ML; 8MG/ML;1.2MG/ML;0.72MG/ML;1.2MG /ML;660 IU/ML;30MCG/ML	N021163	002	Jun 16, 2003	Sep	CMS1	
		AMANTADINE HYDROCHLORIDE							
		CAPSULE;ORAL							
		AMANTADINE HYDROCHLORIDE							
>D>	AB	GRAVITI PHARMS	100MG	A207570	001	Sep 30, 2016	Sep	CAHN	
>A>	AB	INVAGEN PHARMS	100MG	A207570	001	Sep 30, 2016	Sep	CAHN	
		TABLET;ORAL							
		AMANTADINE HYDROCHLORIDE							
>D>	AB	GRAVITI PHARMS	100MG	A207571	001	Jan 31, 2017	Sep	CAHN	
>A>	AB	INVAGEN PHARMS	100MG	A207571	001	Jan 31, 2017	Sep	CAHN	
		AMIKACIN SULFATE							
		INJECTABLE;INJECTION							
		AMIKACIN SULFATE							
>D>	AP	TEVA PHARMS USA	EQ 250MG BASE/ML	A064045	002	Sep 28, 1993	Sep	DISC	
>A>		@	EQ 250MG BASE/ML	A064045	002	Sep 28, 1993	Sep	DISC	
		AMPICILLIN SODIUM							
		INJECTABLE;INJECTION							
		AMPICILLIN SODIUM							
>D>	AP	HOSPIRA INC	EQ 10GM BASE/VIAL	A202865	001	Sep 04, 2015	Sep	DISC	
>A>		@	EQ 10GM BASE/VIAL	A202865	001	Sep 04, 2015	Sep	DISC	

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AMPICILLIN SODIUM; SULBACTAM SODIUM

INJECTABLE;INJECTION

AMPICILLIN AND SULBACTAM

>D>	AP	HOSPIRA INC	EQ 1GM BASE/VIAL;EQ 500MG BASE/VIAL	A090375	001	Dec 21, 2011	Sep	DISC	
>A>		@	EQ 1GM BASE/VIAL;EQ 500MG BASE/VIAL	A090375	001	Dec 21, 2011	Sep	DISC	
>D>	AP		EQ 1GM BASE/VIAL;EQ 500MG BASE/VIAL	A090653	001	Dec 21, 2011	Sep	DISC	
>A>		@	EQ 1GM BASE/VIAL;EQ 500MG BASE/VIAL	A090653	001	Dec 21, 2011	Sep	DISC	
>D>	AP		EQ 2GM BASE/VIAL;EQ 1GM BASE/VIAL	A090375	002	Dec 21, 2011	Sep	DISC	
>A>		@	EQ 2GM BASE/VIAL;EQ 1GM BASE/VIAL	A090375	002	Dec 21, 2011	Sep	DISC	
>D>	AP		EQ 2GM BASE/VIAL;EQ 1GM BASE/VIAL	A090653	002	Dec 21, 2011	Sep	DISC	
>A>		@	EQ 2GM BASE/VIAL;EQ 1GM BASE/VIAL	A090653	002	Dec 21, 2011	Sep	DISC	
>D>	AP		EQ 10GM BASE/VIAL;EQ 5GM BASE/VIAL	A090646	001	Dec 21, 2011	Sep	DISC	
>A>		@	EQ 10GM BASE/VIAL;EQ 5GM BASE/VIAL	A090646	001	Dec 21, 2011	Sep	DISC	
>D>	AP	MUSTAFA NEVZAT ILAC	EQ 1GM BASE/VIAL;EQ 500MG BASE/VIAL	A065316	001	Jun 29, 2007	Sep	DISC	
>A>		@	EQ 1GM BASE/VIAL;EQ 500MG BASE/VIAL	A065316	001	Jun 29, 2007	Sep	DISC	
>D>	AP		EQ 2GM BASE/VIAL;EQ 1GM BASE/VIAL	A065316	002	Jun 29, 2007	Sep	DISC	
>A>		@	EQ 2GM BASE/VIAL;EQ 1GM BASE/VIAL	A065316	002	Jun 29, 2007	Sep	DISC	

ARMODAFINIL

TABLET;ORAL

ARMODAFINIL

>D>	AB	APOTEX INC	50MG	A201514	001	Mar 25, 2019	Sep	DISC	
>A>		@	50MG	A201514	001	Mar 25, 2019	Sep	DISC	
>D>	AB		150MG	A201514	002	Mar 25, 2019	Sep	DISC	
>A>		@	150MG	A201514	002	Mar 25, 2019	Sep	DISC	
>D>	AB		250MG	A201514	003	Mar 25, 2019	Sep	DISC	
>A>		@	250MG	A201514	003	Mar 25, 2019	Sep	DISC	

ARTICAINE HYDROCHLORIDE; EPINEPHRINE BITARTRATE

INJECTABLE;INJECTION

>D>		ARTICAINE HYDROCHLORIDE AND EPINEPHRINE BITARTRATE							
>D>	AP	HOSPIRA	4%;EQ 0.017MG BASE/1.7ML (4%;EQ 0.01MG BASE/ML)	A079138	001	Jun 18, 2010	Sep	DISC	
>A>		@	4%;EQ 0.017MG BASE/1.7ML (4%;EQ 0.01MG BASE/ML)	A079138	001	Jun 18, 2010	Sep	DISC	

ASCORBIC ACID; BIOTIN; CHOLECALCIFEROL; CYANOCOBALAMIN; DEXPANTHENOL; FOLIC ACID; NIACINAMIDE; PYRIDOXINE; RIBOFLAVIN; THIAMINE; TOCOPHEROL HYDROCHLORIDE; VITAMIN A; VITAMIN K

INJECTABLE;INTRAVENOUS

INFUVITE PEDIATRIC (PHARMACY BULK PACKAGE)

>A>	+!	SANDOZ CANADA INC	80MG/VIAL;0.02MG/VIAL;400 IU/VIAL;0.001MG/VIAL;5MG/VIAL;0 .14MG/VIAL;17MG/VIAL;1MG/VIAL;1 .4MG/VIAL;1.2MG/VIAL;7 IU/VIAL;2,300 IU/VIAL;0.2MG/VIAL	N021265	002	Jan 29, 2004	Sep	CMS1	

ATENOLOL

TABLET;ORAL

ATENOLOL

>A>	AB	HLTHCARE	25MG	A074052	001	May 01, 1992	Sep	CAHN	
>A>	AB		50MG	A073025	001	Sep 17, 1991	Sep	CAHN	
>A>	AB		100MG	A073026	001	Sep 17, 1991	Sep	CAHN	
>D>	AB	SANDOZ	25MG	A074052	001	May 01, 1992	Sep	CAHN	
>D>	AB		50MG	A073025	001	Sep 17, 1991	Sep	CAHN	
>D>	AB		100MG	A073026	001	Sep 17, 1991	Sep	CAHN	

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		ATRACURIUM BESYLATE						
		INJECTABLE;INJECTION						
		ATRACURIUM BESYLATE						
>D>	AP	MYLAN LABS LTD	10MG/ML	A206096	001	Jun 22, 2017	Sep	DISC
>A>		@	10MG/ML	A206096	001	Jun 22, 2017	Sep	DISC
		ATRACURIUM BESYLATE PRESERVATIVE FREE						
>D>	AP	MYLAN LABS LTD	10MG/ML	A206001	001	Apr 07, 2017	Sep	DISC
>A>		@	10MG/ML	A206001	001	Apr 07, 2017	Sep	DISC
		AZACITIDINE						
		POWDER;INTRAVENOUS, SUBCUTANEOUS						
		AZACITIDINE						
>D>	AP	LUPIN LTD	100MG/VIAL	A210748	001	Feb 27, 2019	Sep	DISC
>A>		@	100MG/VIAL	A210748	001	Feb 27, 2019	Sep	DISC
>A>		BACLOFEN						
>A>		SOLUTION;ORAL						
>A>		OZOBAX						
>A>		+! METACEL PHARMS LLC	5MG/5ML	N208193	001	Sep 18, 2019	Sep	NEWA
		BARIUM SULFATE						
		SUSPENSION;ORAL						
		READI-CAT 2 SMOOTHIE						
>A>		+! BRACCO	2% (9GM/BOT)	N208143	002	Jan 15, 2016	Sep	CMS1
		READI-CAT 2 SMOOTHIES						
>D>		+! BRACCO	2% (9GM/BOT)	N208143	002	Jan 15, 2016	Sep	CMS1
>D>		BENZYL ALCOHOL						
>D>		LOTION;TOPICAL						
>D>		ULESFIA						
>D>		+! SHIONOGI INC	5%	N022129	001	Apr 09, 2009	Sep	DISC
>A>		+ @	5%	N022129	001	Apr 09, 2009	Sep	DISC
		BEPOTASTINE BESILATE						
		SOLUTION/DROPS;OPHTHALMIC						
		BEPOTASTINE BESILATE						
>D>	AT	APOTEX INC	1.5%	A206066	001	Mar 05, 2019	Sep	DISC
>A>		@	1.5%	A206066	001	Mar 05, 2019	Sep	DISC
		BETAMETHASONE DIPROPIONATE						
		LOTION, AUGMENTED;TOPICAL						
		BETAMETHASONE DIPROPIONATE						
>A>	AB	HI TECH	EQ 0.05% BASE	A208849	001	Oct 11, 2019	Sep	NEWA
		BETAMETHASONE VALERATE						
		LOTION;TOPICAL						
		BETAMETHASONE VALERATE						
>A>	AB	ANIMA	EQ 0.1% BASE	A070052	001	Jul 31, 1985	Sep	CAHN
>D>	AB	STI PHARMA LLC	EQ 0.1% BASE	A070052	001	Jul 31, 1985	Sep	CAHN
		BICALUTAMIDE						
		TABLET;ORAL						
		BICALUTAMIDE						
>D>	AB	TEVA	50MG	A076932	001	Jul 06, 2009	Sep	DISC
>A>		@	50MG	A076932	001	Jul 06, 2009	Sep	DISC
		BUDESONIDE						
		SUSPENSION;INHALATION						
		BUDESONIDE						
>D>	AN	APOTEX INC	0.25MG/2ML	A078202	001	Mar 30, 2009	Sep	CAHN
>D>	AN		0.5MG/2ML	A078202	002	Mar 30, 2009	Sep	CAHN
>A>	AN	NEPHRON	0.25MG/2ML	A078202	001	Mar 30, 2009	Sep	CAHN
>A>	AN		0.5MG/2ML	A078202	002	Mar 30, 2009	Sep	CAHN
		BUPIVACAINE HYDROCHLORIDE						
		INJECTABLE;INJECTION						
		BUPIVACAINE HYDROCHLORIDE						
>D>	AP	MYLAN ASI	0.25%	A091503	001	Oct 18, 2011	Sep	DISC
>A>		@	0.25%	A091503	001	Oct 18, 2011	Sep	DISC
>D>	AP		0.5%	A091503	002	Oct 18, 2011	Sep	DISC
>A>		@	0.5%	A091503	002	Oct 18, 2011	Sep	DISC

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BUPIVACAINE HYDROCHLORIDE
INJECTABLE;INJECTION
BUPIVACAINE HYDROCHLORIDE PRESERVATIVE FREE

>D>	AP	MYLAN ASI	0.25%	A091487	002	Oct 18, 2011	Sep	DISC
>A>		@	0.25%	A091487	002	Oct 18, 2011	Sep	DISC
>D>	AP		0.5%	A091487	001	Oct 18, 2011	Sep	DISC
>A>		@	0.5%	A091487	001	Oct 18, 2011	Sep	DISC
>D>	AP		0.75%	A091487	003	Oct 18, 2011	Sep	DISC
>A>		@	0.75%	A091487	003	Oct 18, 2011	Sep	DISC

BUPIVACAINE HYDROCHLORIDE; EPINEPHRINE BITARTRATE
INJECTABLE;INJECTION
BUPIVACAINE HYDROCHLORIDE AND EPINEPHRINE

>A>		+ @ HOSPIRA	0.5%;0.0091MG/ML	N022046	001	Jul 13, 1983	Sep	CMS1
>D>	AP	SEPTODONT	0.5%;0.0091MG/ML	A077250	001	Sep 27, 2006	Sep	CTEC
>A>			0.5%;0.0091MG/ML	A077250	001	Sep 27, 2006	Sep	CTEC
>A>		!	0.5%;0.0091MG/ML	A077250	001	Sep 27, 2006	Sep	CHRS

BUPIVACAINE HYDROCHLORIDE W/EPINEPHRINE

>D>	AP	+! HOSPIRA	0.5%;0.0091MG/ML	N022046	001	Jul 13, 1983	Sep	DISC
>A>		+ @	0.5%;0.0091MG/ML	N022046	001	Jul 13, 1983	Sep	DISC

BUPRENORPHINE HYDROCHLORIDE
TABLET;SUBLINGUAL
BUPRENORPHINE HYDROCHLORIDE

>D>	AB	MYLAN	EQ 2MG BASE	A201066	001	Mar 06, 2015	Sep	DISC
>A>		@	EQ 2MG BASE	A201066	001	Mar 06, 2015	Sep	DISC
>D>	AB		EQ 8MG BASE	A201066	002	Mar 06, 2015	Sep	DISC
>A>		@	EQ 8MG BASE	A201066	002	Mar 06, 2015	Sep	DISC

BUPROPION HYDROCHLORIDE
TABLET, EXTENDED RELEASE;ORAL
BUPROPION HYDROCHLORIDE

>D>	AB3	SUN PHARM	150MG	A200695	001	Dec 18, 2014	Sep	DISC
>A>		@	150MG	A200695	001	Dec 18, 2014	Sep	DISC

BUSULFAN
INJECTABLE;INJECTION
BUSULFAN

>D>		@ HOSPIRA INC	6MG/ML	A205672	001	Jul 31, 2018	Sep	CMFD
>A>	AP		6MG/ML	A205672	001	Jul 31, 2018	Sep	CMFD

CALCITONIN SALMON
INJECTABLE;INJECTION
CALCIMAR

>D>		@ SANOFI AVENTIS US	200 IU/ML	N017769	001	Apr 17, 1978	Sep	CRLD
>A>		+ @	200 IU/ML	N017769	001	Apr 17, 1978	Sep	CRLD

CALCITRIOL
SOLUTION;ORAL
CALCITRIOL

>A>	AA	ELYSIUM	1MCG/ML	A209798	001	Nov 21, 2018	Sep	CAHN
>D>	AA	INVATECH PHARMA	1MCG/ML	A209798	001	Nov 21, 2018	Sep	CAHN

CALCIUM CHLORIDE; DEXTROSE; MAGNESIUM CHLORIDE; SODIUM CHLORIDE; SODIUM LACTATE
SOLUTION;INTRAPERITONEAL
DIANEAL LOW CALCIUM W/ DEXTROSE 3.5% IN PLASTIC CONTAINER

>D>		+ BAXTER HLTHCARE	18.3MG/100ML;3.5GM/100ML;5.08MG /100ML;538MG/100ML;448MG/100ML	N020183	003	Dec 04, 1992	Sep	DISC
>A>		+ @	18.3MG/100ML;3.5GM/100ML;5.08MG /100ML;538MG/100ML;448MG/100ML	N020183	003	Dec 04, 1992	Sep	DISC

CEFEPIME HYDROCHLORIDE
INJECTABLE;INJECTION
CEFEPIME HYDROCHLORIDE

>D>	AP	HOSPIRA INC	EQ 500MG BASE/VIAL	A065369	001	Jun 18, 2007	Sep	DISC
>A>		@	EQ 500MG BASE/VIAL	A065369	001	Jun 18, 2007	Sep	DISC
>D>	AP		EQ 1GM BASE/VIAL	A065369	002	Jun 18, 2007	Sep	DISC
>A>		@	EQ 1GM BASE/VIAL	A065369	002	Jun 18, 2007	Sep	DISC
>D>	AP		EQ 1GM BASE/VIAL	A202268	001	Jul 30, 2012	Sep	DISC

CEFEPIME HYDROCHLORIDE
INJECTABLE;INJECTION
CEFEPIME HYDROCHLORIDE

>A>	@	EQ 1GM BASE/VIAL	A202268	001	Jul 30, 2012	Sep	DISC	
>D>	AP	EQ 2GM BASE/VIAL	A065369	003	Jun 18, 2007	Sep	DISC	
>A>	@	EQ 2GM BASE/VIAL	A065369	003	Jun 18, 2007	Sep	DISC	
>D>	AP	EQ 2GM BASE/VIAL	A202268	002	Jul 30, 2012	Sep	DISC	
>A>	@	EQ 2GM BASE/VIAL	A202268	002	Jul 30, 2012	Sep	DISC	

CEFOTAXIME SODIUM
INJECTABLE;INJECTION
CEFOTAXIME SODIUM

>D>	AP HOSPIRA INC	EQ 500MG BASE/VIAL	A065290	001	Aug 11, 2006	Sep	DISC	
>A>	@	EQ 500MG BASE/VIAL	A065290	001	Aug 11, 2006	Sep	DISC	
>D>	AP	EQ 1GM BASE/VIAL	A065290	002	Aug 11, 2006	Sep	DISC	
>A>	@	EQ 1GM BASE/VIAL	A065290	002	Aug 11, 2006	Sep	DISC	
>D>	AP	EQ 1GM BASE/VIAL	A065293	001	Aug 10, 2006	Sep	DISC	
>A>	@	EQ 1GM BASE/VIAL	A065293	001	Aug 10, 2006	Sep	DISC	
>D>	AP	EQ 1GM BASE/VIAL	A203132	001	Feb 19, 2016	Sep	DISC	
>A>	@	EQ 1GM BASE/VIAL	A203132	001	Feb 19, 2016	Sep	DISC	
>D>	AP	EQ 2GM BASE/VIAL	A065290	003	Aug 11, 2006	Sep	DISC	
>A>	@	EQ 2GM BASE/VIAL	A065290	003	Aug 11, 2006	Sep	DISC	
>D>	AP	EQ 2GM BASE/VIAL	A065293	002	Aug 10, 2006	Sep	DISC	
>A>	@	EQ 2GM BASE/VIAL	A065293	002	Aug 10, 2006	Sep	DISC	
>D>	AP	EQ 2GM BASE/VIAL	A203132	002	Feb 19, 2016	Sep	DISC	
>A>	@	EQ 2GM BASE/VIAL	A203132	002	Feb 19, 2016	Sep	DISC	

CEFOXITIN SODIUM
INJECTABLE;INJECTION
CEFOXITIN

>D>	AP HOSPIRA INC	EQ 1GM BASE/VIAL	A065313	001	Jan 23, 2006	Sep	DISC	
>A>	@	EQ 1GM BASE/VIAL	A065313	001	Jan 23, 2006	Sep	DISC	
>D>	AP	EQ 2GM BASE/VIAL	A065313	002	Jan 23, 2006	Sep	DISC	
>A>	@	EQ 2GM BASE/VIAL	A065313	002	Jan 23, 2006	Sep	DISC	
>D>	AP	EQ 10GM BASE/VIAL	A065312	001	Feb 13, 2006	Sep	DISC	
>A>	@	EQ 10GM BASE/VIAL	A065312	001	Feb 13, 2006	Sep	DISC	

CEFUROXIME SODIUM
INJECTABLE;INJECTION
CEFUROXIME SODIUM

>D>	AP HOSPIRA INC	EQ 1.5GM BASE/VIAL	A065483	002	Oct 15, 2008	Sep	DISC	
>A>	@	EQ 1.5GM BASE/VIAL	A065483	002	Oct 15, 2008	Sep	DISC	
>D>	AP	EQ 1.5GM BASE/VIAL	A065503	001	Oct 15, 2008	Sep	DISC	
>A>	@	EQ 1.5GM BASE/VIAL	A065503	001	Oct 15, 2008	Sep	DISC	
>D>	AP	EQ 7.5GM BASE/VIAL	A065484	001	Oct 15, 2008	Sep	DISC	
>A>	@	EQ 7.5GM BASE/VIAL	A065484	001	Oct 15, 2008	Sep	DISC	

INJECTABLE;INTRAMUSCULAR, INTRAVENOUS
CEFUROXIME SODIUM

>D>	AP HOSPIRA INC	EQ 750MG BASE/VIAL	A065483	001	Oct 15, 2008	Sep	DISC	
>A>	@	EQ 750MG BASE/VIAL	A065483	001	Oct 15, 2008	Sep	DISC	

CHLORPROMAZINE HYDROCHLORIDE
CONCENTRATE;ORAL
CHLORPROMAZINE HYDROCHLORIDE INTENSOL

>D>	@ CYCLE PHARMS LTD	30MG/ML	A088157	001	Apr 27, 1983	Sep	CAHN	
>D>	@	100MG/ML	A088158	001	Apr 27, 1983	Sep	CAHN	
>A>	@ HIKMA	30MG/ML	A088157	001	Apr 27, 1983	Sep	CAHN	
>A>	@	100MG/ML	A088158	001	Apr 27, 1983	Sep	CAHN	

CHLORTHALIDONE
TABLET;ORAL
CHLORTHALIDONE

>D>	AB APPCO PHARMA LLC	25MG	A210742	001	Oct 12, 2018	Sep	CAHN	
>D>	AB	50MG	A210742	002	Oct 12, 2018	Sep	CAHN	
>A>	AB ARISE	25MG	A210742	001	Oct 12, 2018	Sep	CAHN	
>A>	AB	50MG	A210742	002	Oct 12, 2018	Sep	CAHN	

		CHLORZOXAZONE							
		TABLET;ORAL							
		CHLORZOXAZONE							
>A>	AA	NOVITIUM PHARMA	500MG	A212254	001	Sep 12, 2019	Sep	NEWA	
>D>	!	WATSON LABS	500MG	A089859	001	May 04, 1988	Sep	CTEC	
>A>	AA !		500MG	A089859	001	May 04, 1988	Sep	CTEC	
		CICLOPIROX							
		SOLUTION;TOPICAL							
		CICLOPIROX							
>D>	AT	INGENUS PHARMS LLC	8%	A078124	001	Sep 18, 2007	Sep	CAHN	
>A>	AT	NOVAST LABS	8%	A078124	001	Sep 18, 2007	Sep	CAHN	
		CILASTATIN SODIUM; IMIPENEM							
		POWDER;INTRAVENOUS							
		IMIPENEM AND CILASTATIN							
>D>	AP	HOSPIRA INC	EQ 500MG BASE/VIAL;500MG/VIAL	A090825	002	Nov 16, 2011	Sep	DISC	
>A>	@		EQ 500MG BASE/VIAL;500MG/VIAL	A090825	002	Nov 16, 2011	Sep	DISC	
>D>	AP		EQ 500MG BASE/VIAL;500MG/VIAL	A091007	001	Nov 16, 2011	Sep	DISC	
>A>	@		EQ 500MG BASE/VIAL;500MG/VIAL	A091007	001	Nov 16, 2011	Sep	DISC	
		CIPROFLOXACIN HYDROCHLORIDE							
		TABLET;ORAL							
		CIPROFLOXACIN HYDROCHLORIDE							
>A>	AB	CHARTWELL	EQ 250MG BASE	A076896	001	Nov 04, 2004	Sep	CAHN	
>A>	AB		EQ 500MG BASE	A076896	002	Nov 04, 2004	Sep	CAHN	
>A>	AB		EQ 750MG BASE	A076896	003	Nov 04, 2004	Sep	CAHN	
>D>	AB	CHARTWELL MOLECULES	EQ 250MG BASE	A076896	001	Nov 04, 2004	Sep	CAHN	
>D>	AB		EQ 500MG BASE	A076896	002	Nov 04, 2004	Sep	CAHN	
>D>	AB		EQ 750MG BASE	A076896	003	Nov 04, 2004	Sep	CAHN	
		CISATRACURIUM BESYLATE							
		INJECTABLE;INJECTION							
		CISATRACURIUM BESYLATE							
>A>	AP	ANDA REPOSITORY	EQ 2MG BASE/ML	A209132	001	Apr 24, 2019	Sep	CAHN	
>D>	AP	SOMERSET THERAPS LLC	EQ 2MG BASE/ML	A209132	001	Apr 24, 2019	Sep	CAHN	
>D>		CITRIC ACID; MAGNESIUM OXIDE; SODIUM PICOSULFATE							
>D>		FOR SOLUTION;ORAL							
>D>		PREPOPIK							
>D>	+!	FERRING PHARMS INC	12GM/PACKET;3.5GM/PACKET;10MG/PACKET	N202535	001	Jul 16, 2012	Sep	DISC	
>A>	+ @		12GM/PACKET;3.5GM/PACKET;10MG/PACKET	N202535	001	Jul 16, 2012	Sep	DISC	
		CLARITHROMYCIN							
		TABLET;ORAL							
		CLARITHROMYCIN							
>D>	AB	AJANTA PHARMA LTD	250MG	A206714	001	Apr 25, 2019	Sep	DISC	
>A>	@		250MG	A206714	001	Apr 25, 2019	Sep	DISC	
>D>	AB		500MG	A206714	002	Apr 25, 2019	Sep	DISC	
>A>	@		500MG	A206714	002	Apr 25, 2019	Sep	DISC	
		CLOBAZAM							
		SUSPENSION;ORAL							
		CLOBAZAM							
>D>	AB	TARO	2.5MG/ML	A210978	001	Apr 15, 2019	Sep	DISC	
>A>	@		2.5MG/ML	A210978	001	Apr 15, 2019	Sep	DISC	
		CLOBETASOL PROPIONATE							
		CREAM;TOPICAL							
		CLOBETASOL PROPIONATE							
>A>	AB1	RISING	0.05%	A211401	001	Jan 11, 2019	Sep	CAHN	
>D>	AB1	SOLARIS PHARMA CORP	0.05%	A211401	001	Jan 11, 2019	Sep	CAHN	
		LOTION;TOPICAL							
		CLOBETASOL PROPIONATE							
>A>	AB	ZYDUS PHARMS	0.05%	A205249	001	Sep 24, 2019	Sep	NEWA	
		SOLUTION;TOPICAL							
		CLOBETASOL PROPIONATE							
>A>	AT	SAPTALIS PHARMS	0.05%	A211494	001	Oct 02, 2019	Sep	NEWA	

		CLOBETASOL PROPIONATE							
		SPRAY;TOPICAL							
		CLOBETASOL PROPIONATE							
>A>	AT	ALEOR DERMACEUTICALS	0.05%	A211191	001	Oct 02, 2019	Sep	NEWA	
		CLOPIDOGREL BISULFATE							
		TABLET;ORAL							
		CLOPIDOGREL BISULFATE							
>D>	AB	MYLAN PHARMS INC	EQ 75MG BASE	A077665	001	May 17, 2012	Sep	DISC	
>A>		@	EQ 75MG BASE	A077665	001	May 17, 2012	Sep	DISC	
>A>		COBICISTAT; DARUNAVIR							
>A>		TABLET;ORAL							
>A>		PREZCOBIX							
>A>		+! JANSSEN PRODS	150MG;800MG	N205395	001	Jan 29, 2015	Sep	CAIN	
>D>		COBICISTAT; DARUNAVIR ETHANOLATE							
>D>		TABLET;ORAL							
>D>		PREZCOBIX							
>D>		+! JANSSEN PRODS	150MG;EQ 800MG BASE	N205395	001	Jan 29, 2015	Sep	CAIN	
		COLCHICINE							
		TABLET;ORAL							
		COLCHICINE							
>A>	AB	MYLAN	0.6MG	A209470	001	Sep 16, 2019	Sep	NEWA	
		COLESEVELAM HYDROCHLORIDE							
		TABLET;ORAL							
		COLESEVELAM HYDROCHLORIDE							
>A>	AB	BIONPHARMA INC	625MG	A208670	001	Sep 13, 2019	Sep	NEWA	
>A>	AB	ZYDUS PHARMS	625MG	A207765	001	Oct 07, 2019	Sep	NEWA	
		CYPROHEPTADINE HYDROCHLORIDE							
		SYRUP;ORAL							
		CYPROHEPTADINE HYDROCHLORIDE							
>A>	AA	ANDA REPOSITORY	2MG/5ML	A204823	001	Dec 27, 2016	Sep	CAHN	
>A>	AA	ELYSIUM	2MG/5ML	A209108	001	Oct 16, 2018	Sep	CAHN	
>D>	AA	INVATECH PHARMA	2MG/5ML	A209108	001	Oct 16, 2018	Sep	CAHN	
>D>	AA	PATRIN PHARMA INC	2MG/5ML	A204823	001	Dec 27, 2016	Sep	CAHN	
		TABLET;ORAL							
		CYPROHEPTADINE HYDROCHLORIDE							
>D>	AA	APNAR PHARMA LP	4MG	A207555	001	Jan 31, 2017	Sep	CAHN	
>A>	AA	ELYSIUM	4MG	A207555	001	Jan 31, 2017	Sep	CAHN	
		CYTARABINE							
		INJECTABLE;INJECTION							
		CYTARABINE							
>D>	AP	MYLAN LABS LTD	20MG/ML	A200916	001	Dec 13, 2011	Sep	DISC	
>A>		@	20MG/ML	A200916	001	Dec 13, 2011	Sep	DISC	
>A>		DARUNAVIR							
>A>		SUSPENSION;ORAL							
>A>		PREZISTA							
>A>		+! JANSSEN PRODS	100MG/ML	N202895	001	Dec 16, 2011	Sep	CAIN	
>A>		TABLET;ORAL							
>A>		DARUNAVIR ETHANOLATE							
>A>	AB	TEVA PHARMS USA	600MG	A202118	001	Nov 21, 2017	Sep	CAIN	
>A>		PREZISTA							
>A>		+ JANSSEN PRODS	75MG	N021976	004	Dec 18, 2008	Sep	CAIN	
>A>		+	150MG	N021976	005	Dec 18, 2008	Sep	CAIN	
>A>		+ @	300MG	N021976	001	Jun 23, 2006	Sep	CAIN	
>A>		+ @	400MG	N021976	003	Oct 21, 2008	Sep	CAIN	
>A>	AB	+	600MG	N021976	002	Feb 25, 2008	Sep	CAIN	
>A>		+!	800MG	N021976	006	Nov 09, 2012	Sep	CAIN	
>D>		DARUNAVIR ETHANOLATE							
>D>		SUSPENSION;ORAL							
>D>		PREZISTA							
>D>		+! JANSSEN PRODS	EQ 100MG BASE/ML	N202895	001	Dec 16, 2011	Sep	CAIN	

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>D>		DARUNAVIR ETHANOLATE							
>D>		TABLET;ORAL							
>D>		DARUNAVIR ETHANOLATE							
>D>	AB	TEVA PHARMS USA	EQ 600MG BASE	A202118	001	Nov 21, 2017	Sep	CAIN	
>D>		PREZISTA							
>D>		+ JANSSEN PRODS	EQ 75MG BASE	N021976	004	Dec 18, 2008	Sep	CAIN	
>D>		+	EQ 150MG BASE	N021976	005	Dec 18, 2008	Sep	CAIN	
>D>		+ @	EQ 300MG BASE	N021976	001	Jun 23, 2006	Sep	CAIN	
>D>		+ @	EQ 400MG BASE	N021976	003	Oct 21, 2008	Sep	CAIN	
>D>	AB	+	EQ 600MG BASE	N021976	002	Feb 25, 2008	Sep	CAIN	
>D>		+!	EQ 800MG BASE	N021976	006	Nov 09, 2012	Sep	CAIN	
		DECITABINE							
		INJECTABLE;INTRAVENOUS							
		DECITABINE							
>A>	AP	INGENUS PHARMS LLC	50MG/VIAL	A210984	001	Sep 16, 2019	Sep	NEWA	
		DESIPRAMINE HYDROCHLORIDE							
		TABLET;ORAL							
		DESIPRAMINE HYDROCHLORIDE							
>D>	AB	INGENUS PHARMS LLC	10MG	A204963	001	Dec 26, 2017	Sep	CAHN	
>D>	AB		25MG	A204963	002	Dec 26, 2017	Sep	CAHN	
>D>	AB		50MG	A204963	003	Dec 26, 2017	Sep	CAHN	
>D>	AB		75MG	A204963	004	Dec 26, 2017	Sep	CAHN	
>D>	AB		100MG	A204963	005	Dec 26, 2017	Sep	CAHN	
>D>	AB		150MG	A204963	006	Dec 26, 2017	Sep	CAHN	
>A>	AB	NOVAST LABS	10MG	A204963	001	Dec 26, 2017	Sep	CAHN	
>A>	AB		25MG	A204963	002	Dec 26, 2017	Sep	CAHN	
>A>	AB		50MG	A204963	003	Dec 26, 2017	Sep	CAHN	
>A>	AB		75MG	A204963	004	Dec 26, 2017	Sep	CAHN	
>A>	AB		100MG	A204963	005	Dec 26, 2017	Sep	CAHN	
>A>	AB		150MG	A204963	006	Dec 26, 2017	Sep	CAHN	
		DEXAMETHASONE							
		ELIXIR;ORAL							
		DEXAMETHASONE							
>A>	AA	! ANIMA	0.5MG/5ML	A084754	001	Sep 21, 1976	Sep	CAHN	
>D>	AA	! STI PHARMA LLC	0.5MG/5ML	A084754	001	Sep 21, 1976	Sep	CAHN	
		DEXAMETHASONE SODIUM PHOSPHATE							
		INJECTABLE;INJECTION							
		DEXAMETHASONE SODIUM PHOSPHATE							
>A>	AP	ANDA REPOSITORY	EQ 4MG PHOSPHATE/ML	A207521	001	Jun 08, 2018	Sep	CAHN	
>D>	AP	SOMERSET THERAPS LLC	EQ 4MG PHOSPHATE/ML	A207521	001	Jun 08, 2018	Sep	CAHN	
		DEXTROSE							
		INJECTABLE;INJECTION							
>D>		DEXTROSE 70% IN PLASTIC CONTAINER							
>D>	AP	+! BAXTER HLTHCARE	70GM/100ML	N017521	006	Mar 26, 1982	Sep	DISC	
>A>		+ @	70GM/100ML	N017521	006	Mar 26, 1982	Sep	DISC	
		DICLOFENAC SODIUM; MISOPROSTOL							
		TABLET, DELAYED RELEASE;ORAL							
		DICLOFENAC SODIUM AND MISOPROSTOL							
>D>	AB	EXELA HOLDINGS	50MG;0.2MG	A200540	001	Mar 14, 2014	Sep	DISC	
>A>		@	50MG;0.2MG	A200540	001	Mar 14, 2014	Sep	DISC	
>D>	AB		75MG;0.2MG	A200540	002	Mar 14, 2014	Sep	DISC	
>A>		@	75MG;0.2MG	A200540	002	Mar 14, 2014	Sep	DISC	
		DICYCLOMINE HYDROCHLORIDE							
		INJECTABLE;INJECTION							
		DICYCLOMINE HYDROCHLORIDE							
>D>		@ APC PHARMS LLC	10MG/ML	A210979	001	Jul 02, 2018	Sep	CAHN	
>A>		@ FOSUN PHARMA	10MG/ML	A210979	001	Jul 02, 2018	Sep	CAHN	

DIGOXIN
ELIXIR;ORAL
DIGOXIN

>D>		+! HIKMA	0.05MG/ML	N021648	001	Aug 26, 2004	Sep	CFTG
>A>	AA	+!	0.05MG/ML	N021648	001	Aug 26, 2004	Sep	CFTG
>A>	AA	NOVITIUM PHARMA	0.05MG/ML	A213000	001	Oct 04, 2019	Sep	NFTG

DIVALPROEX SODIUM
TABLET, DELAYED RELEASE;ORAL
DIVALPROEX SODIUM

>D>	AB	TEVA	EQ 125MG VALPROIC ACID	A076941	001	Jul 29, 2008	Sep	DISC
>A>		@	EQ 125MG VALPROIC ACID	A076941	001	Jul 29, 2008	Sep	DISC
>D>	AB		EQ 250MG VALPROIC ACID	A076941	002	Jul 29, 2008	Sep	DISC
>A>		@	EQ 250MG VALPROIC ACID	A076941	002	Jul 29, 2008	Sep	DISC
>D>	AB		EQ 500MG VALPROIC ACID	A076941	003	Jul 29, 2008	Sep	DISC
>A>		@	EQ 500MG VALPROIC ACID	A076941	003	Jul 29, 2008	Sep	DISC

TABLET, EXTENDED RELEASE;ORAL
DIVALPROEX SODIUM

>D>	AB	ANCHEN PHARMS	EQ 250MG VALPROIC ACID	A078445	001	Feb 26, 2009	Sep	DISC
>A>		@	EQ 250MG VALPROIC ACID	A078445	001	Feb 26, 2009	Sep	DISC
>D>	AB		EQ 500MG VALPROIC ACID	A078445	002	Aug 04, 2009	Sep	DISC
>A>		@	EQ 500MG VALPROIC ACID	A078445	002	Aug 04, 2009	Sep	DISC

DORZOLAMIDE HYDROCHLORIDE; TIMOLOL MALEATE
SOLUTION/DROPS;OPHTHALMIC
DORZOLAMIDE HYDROCHLORIDE AND TIMOLOL MALEATE

>A>	AT	ANDA REPOSITORY	EQ 2% BASE;EQ 0.5% BASE	A207523	001	Jun 25, 2019	Sep	CAHN
>D>	AT	SOMERSET THERAPS LLC	EQ 2% BASE;EQ 0.5% BASE	A207523	001	Jun 25, 2019	Sep	CAHN

DOXEPIN HYDROCHLORIDE
CAPSULE;ORAL
DOXEPIN HYDROCHLORIDE

>A>	AB	AJANTA PHARMA LTD	EQ 10MG BASE	A212624	001	Sep 13, 2019	Sep	NEWA
>A>	AB		EQ 25MG BASE	A212624	002	Sep 13, 2019	Sep	NEWA
>A>	AB		EQ 50MG BASE	A212624	003	Sep 13, 2019	Sep	NEWA
>A>	AB		EQ 75MG BASE	A212624	004	Sep 13, 2019	Sep	NEWA
>A>	AB		EQ 100MG BASE	A212624	005	Sep 13, 2019	Sep	NEWA

DOXERCALCIFEROL
INJECTABLE;INJECTION
DOXERCALCIFEROL

>A>	AP	GLAND PHARMA LTD	4MCG/2ML (2MCG/ML)	A210452	001	Sep 26, 2019	Sep	NEWA

DOXORUBICIN HYDROCHLORIDE
INJECTABLE;INJECTION
DOXORUBICIN HYDROCHLORIDE

>A>		@ HLTHCARE	2MG/ML	A200146	001	Jul 18, 2012	Sep	CAHN
>D>	AP	MYLAN LABS LTD	2MG/ML	A200901	001	Feb 14, 2012	Sep	DISC
>A>		@	2MG/ML	A200901	001	Feb 14, 2012	Sep	DISC
>D>		@ SANDOZ INC	2MG/ML	A200146	001	Jul 18, 2012	Sep	CAHN

DOXYCYCLINE HYCLATE
CAPSULE;ORAL
DOXYCYCLINE HYCLATE

>A>	AB	CHANGZHOU PHARM	EQ 100MG BASE	A209402	001	Oct 07, 2019	Sep	NEWA

TABLET, DELAYED RELEASE;ORAL
DOXYCYCLINE HYCLATE

>D>	AB	MYLAN PHARMS INC	EQ 150MG BASE	A091052	001	Feb 08, 2012	Sep	DISC
>A>		@	EQ 150MG BASE	A091052	001	Feb 08, 2012	Sep	DISC

TABLET;ORAL
DOXYCYCLINE HYCLATE

>A>	AB	CHANGZHOU PHARM	EQ 100MG BASE	A211343	001	Oct 09, 2019	Sep	NEWA

ENTECAVIR
TABLET;ORAL
ENTECAVIR

>A>	AB	BRIGHTGENE	0.5MG	A212126	001	Sep 25, 2019	Sep	NEWA
>A>	AB		1MG	A212126	002	Sep 25, 2019	Sep	NEWA

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EPIRUBICIN HYDROCHLORIDE
INJECTABLE;INJECTION
EPIRUBICIN HYDROCHLORIDE

>D>	AP		ACTAVIS TOTOWA	10MG/5ML (2MG/ML)	A065445	001	Sep 18, 2008	Sep	DISC
>A>		@		10MG/5ML (2MG/ML)	A065445	001	Sep 18, 2008	Sep	DISC
>D>	AP		FRESENIUS KABI USA	10MG/5ML (2MG/ML)	A065408	001	Oct 15, 2007	Sep	CTEC
>A>				10MG/5ML (2MG/ML)	A065408	001	Oct 15, 2007	Sep	CTEC
>D>		@	MUSTAFA NEVSAT	50MG/25ML (2MG/ML)	A090266	001	Apr 15, 2011	Sep	CAHN
>D>		@		200MG/100ML (2MG/ML)	A090266	002	Apr 15, 2011	Sep	CAHN
>D>	AP		MYLAN LABS LTD	50MG/25ML (2MG/ML)	A091599	001	Mar 12, 2012	Sep	DISC
>A>		@		50MG/25ML (2MG/ML)	A091599	001	Mar 12, 2012	Sep	DISC
>D>	AP			200MG/100ML (2MG/ML)	A091599	002	Mar 12, 2012	Sep	DISC
>A>		@		200MG/100ML (2MG/ML)	A091599	002	Mar 12, 2012	Sep	DISC
>A>		@	ZENNOVA	50MG/25ML (2MG/ML)	A090266	001	Apr 15, 2011	Sep	CAHN
>A>		@		200MG/100ML (2MG/ML)	A090266	002	Apr 15, 2011	Sep	CAHN

ERYTHROMYCIN ETHYLSUCCINATE
GRANULE;ORAL
E.E.S.

>D>	AB1	+	ARBOR PHARMS LLC	EQ 200MG BASE/5ML	N050207	001	Apr 02, 1965	Sep	CTEC
>A>	AB	+		EQ 200MG BASE/5ML	N050207	001	Apr 02, 1965	Sep	CTEC

ERYPED

>D>	AB2	+	ARBOR PHARMS LLC	EQ 200MG BASE/5ML	N050207	003	Mar 30, 1987	Sep	CTEC
>A>	AB	+		EQ 200MG BASE/5ML	N050207	003	Mar 30, 1987	Sep	CTEC

ERYTHROMYCIN ETHYLSUCCINATE

>D>	AB1		ANI PHARMS INC	EQ 200MG BASE/5ML	A062055	001	Nov 27, 1978	Sep	CTEC
>A>	AB			EQ 200MG BASE/5ML	A062055	001	Nov 27, 1978	Sep	CTEC
>D>	AB2			EQ 200MG BASE/5ML	A062055	003	Nov 02, 2018	Sep	CTEC
>A>	AB			EQ 200MG BASE/5ML	A062055	003	Nov 02, 2018	Sep	CTEC

ESCITALOPRAM OXALATE
SOLUTION;ORAL
ESCITALOPRAM OXALATE

>A>	AA		ALLIED	EQ 5MG BASE/5ML	A203967	001	May 26, 2015	Sep	CAHN
>D>	AA		ANTRIM PHARMS LLC	EQ 5MG BASE/5ML	A203967	001	May 26, 2015	Sep	CAHN

ETHINYL ESTRADIOL; NORETHINDRONE
TABLET;ORAL-28
NORETHINDRONE AND ETHINYL ESTRADIOL

>D>		!	MYLAN LABS LTD	0.05MG;1MG	A203006	001	Aug 05, 2013	Sep	DISC
>A>		@		0.05MG;1MG	A203006	001	Aug 05, 2013	Sep	DISC

ETHINYL ESTRADIOL; NORGESTIMATE
TABLET;ORAL-28
NORGESTIMATE AND ETHINYL ESTRADIOL

>A>	AB		NAARI PTE LTD	0.035MG;0.035MG;0.035MG;0.18MG;0.215MG;0.25MG	A200383	001	Apr 07, 2015	Sep	CAHN
>A>	AB			0.035MG;0.25MG	A200384	001	Apr 07, 2015	Sep	CAHN
>D>	AB		OC PHARMA	0.035MG;0.18MG;0.215MG;0.25MG	A200383	001	Apr 07, 2015	Sep	CAHN
>D>	AB			0.035MG;0.25MG	A200384	001	Apr 07, 2015	Sep	CAHN

FEBUXOSTAT
TABLET;ORAL
FEBUXOSTAT

>A>	AB		WEST-WARD PHARMS INT	40MG	A205414	001	Oct 15, 2019	Sep	NEWA
>A>	AB			80MG	A205414	002	Oct 15, 2019	Sep	NEWA

FENOFIBRATE
CAPSULE;ORAL
FENOFIBRATE (MICRONIZED)

>D>	AB		INGENUS PHARMS LLC	67MG	A207564	001	Apr 19, 2019	Sep	CAHN
>D>	AB			134MG	A207564	002	Apr 19, 2019	Sep	CAHN
>D>	AB			200MG	A207564	003	Apr 19, 2019	Sep	CAHN
>A>	AB		NOVAST LABS	67MG	A207564	001	Apr 19, 2019	Sep	CAHN
>A>	AB			134MG	A207564	002	Apr 19, 2019	Sep	CAHN
>A>	AB			200MG	A207564	003	Apr 19, 2019	Sep	CAHN

TABLET;ORAL
FENOFIBRATE

>D>	AB		APPCO PHARMA LLC	54MG	A210670	001	Sep 06, 2019	Sep	CAHN
>D>	AB			160MG	A210670	002	Sep 06, 2019	Sep	CAHN

FENOFIBRATE
TABLET;ORAL
FENOFIBRATE

>A>	AB	NUVO PHARM	54MG	A210670	001	Sep 06, 2019	Sep	CAHN
>A>	AB		160MG	A210670	002	Sep 06, 2019	Sep	CAHN
>D>		TRIGLIDE						
>D>	BX	+! SKYEPHARMA AG	160MG	N021350	002	May 07, 2005	Sep	DISC
>A>		+ @	160MG	N021350	002	May 07, 2005	Sep	DISC

FENTANYL
SPRAY;SUBLINGUAL
SUBSYS

>A>		+ BTCP PHARMA	0.1MG	N202788	001	Jan 04, 2012	Sep	CAHN
>A>		+	0.2MG	N202788	002	Jan 04, 2012	Sep	CAHN
>A>		+!	0.4MG	N202788	003	Jan 04, 2012	Sep	CAHN
>A>		+	0.6MG	N202788	004	Jan 04, 2012	Sep	CAHN
>A>		+	0.8MG	N202788	005	Jan 04, 2012	Sep	CAHN
>A>		+	1.2MG	N202788	006	Aug 30, 2012	Sep	CAHN
>A>		+	1.6MG	N202788	007	Aug 30, 2012	Sep	CAHN
>D>		+ INSYS DEV CO INC	0.1MG	N202788	001	Jan 04, 2012	Sep	CAHN
>D>		+	0.2MG	N202788	002	Jan 04, 2012	Sep	CAHN
>D>		+!	0.4MG	N202788	003	Jan 04, 2012	Sep	CAHN
>D>		+	0.6MG	N202788	004	Jan 04, 2012	Sep	CAHN
>D>		+	0.8MG	N202788	005	Jan 04, 2012	Sep	CAHN
>D>		+	1.2MG	N202788	006	Aug 30, 2012	Sep	CAHN
>D>		+	1.6MG	N202788	007	Aug 30, 2012	Sep	CAHN

FENTANYL CITRATE
SPRAY, METERED;NASAL
LAZANDA

>A>		+ BTCP PHARMA	EQ 0.1MG BASE	N022569	001	Jun 30, 2011	Sep	CAHN
>A>		+ @	EQ 0.3MG BASE	N022569	003	Dec 21, 2015	Sep	DISC
>A>		+ @	EQ 0.3MG BASE	N022569	003	Dec 21, 2015	Sep	CAHN
>A>		+!	EQ 0.4MG BASE	N022569	002	Jun 30, 2011	Sep	CAHN
>D>		+ ELEFSEE PHARMS INTL	EQ 0.1MG BASE	N022569	001	Jun 30, 2011	Sep	CAHN
>D>		+	EQ 0.3MG BASE	N022569	003	Dec 21, 2015	Sep	CAHN
>D>		+!	EQ 0.4MG BASE	N022569	002	Jun 30, 2011	Sep	CAHN

FLUCONAZOLE
FOR SUSPENSION;ORAL
FLUCONAZOLE

>D>	AB	IVAX SUB TEVA PHARMS	50MG/5ML	A077523	001	Sep 12, 2007	Sep	DISC
>A>		@	50MG/5ML	A077523	001	Sep 12, 2007	Sep	DISC
>D>	AB		200MG/5ML	A077523	002	Sep 12, 2007	Sep	DISC
>A>		@	200MG/5ML	A077523	002	Sep 12, 2007	Sep	DISC

FLUOCINOLONE ACETONIDE
OIL/DROPS;OTIC
FLAC

>A>	AT	ANDA REPOSITORY	0.01%	A210736	001	Apr 11, 2018	Sep	CAHN
>D>	AT	PATRIN PHARMA INC	0.01%	A210736	001	Apr 11, 2018	Sep	CAHN

FLUOROURACIL
INJECTABLE;INJECTION
FLUOROURACIL

>D>	AP	MYLAN LABS LTD	500MG/10ML (50MG/ML)	A202668	001	Jul 17, 2012	Sep	DISC
>A>		@	500MG/10ML (50MG/ML)	A202668	001	Jul 17, 2012	Sep	DISC
>D>	AP		1GM/20ML (50MG/ML)	A202668	002	Jul 17, 2012	Sep	DISC
>A>		@	1GM/20ML (50MG/ML)	A202668	002	Jul 17, 2012	Sep	DISC

FLUOXETINE HYDROCHLORIDE
TABLET;ORAL
FLUOXETINE HYDROCHLORIDE

>D>	AB	APPCO PHARMA LLC	EQ 60MG BASE	A211477	001	Nov 21, 2018	Sep	CAHN
>A>	AB	TARO	EQ 60MG BASE	A211477	001	Nov 21, 2018	Sep	CAHN

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		FLUTICASONE PROPIONATE							
		POWDER;INHALATION							
>D>		ARMONAIR RESPICLICK							
>D>		+ TEVA PHARM	0.055MG/INH	N208798	001	Jan 27, 2017	Sep	DISC	
>A>		+ @	0.055MG/INH	N208798	001	Jan 27, 2017	Sep	DISC	
>D>		+!	0.232MG/INH	N208798	003	Jan 27, 2017	Sep	DISC	
>A>		+ @	0.232MG/INH	N208798	003	Jan 27, 2017	Sep	DISC	
		FOSAPREPITANT							
		POWDER;INTRAVENOUS							
		FOSAPREPITANT DIMEGLUMINE							
>A>		TEVA PHARMS USA	150MG/VIAL	N210064	001	Sep 05, 2019	Sep	NEWA	
		FUROSEMIDE							
		TABLET;ORAL							
		FUROSEMIDE							
>A>		@ ANI PHARMS INC	40MG	A070413	001	Feb 26, 1986	Sep	CAHN	
>D>		@ WATSON LABS INC	40MG	A070413	001	Feb 26, 1986	Sep	CAHN	
		GADOPENTETATE DIMEGLUMINE							
		INJECTABLE;INJECTION							
		MAGNEVIST							
>D>		+! BAYER HLTHCARE	469.01MG/ML	N019596	001	Jun 02, 1988	Sep	DISC	
>A>		+ @	469.01MG/ML	N019596	001	Jun 02, 1988	Sep	DISC	
>D>		+!	469.01MG/ML	N021037	001	Mar 10, 2000	Sep	DISC	
>A>		+ @	469.01MG/ML	N021037	001	Mar 10, 2000	Sep	DISC	
		GALANTAMINE HYDROBROMIDE							
		TABLET;ORAL							
		GALANTAMINE HYDROBROMIDE							
>D>	AB	HERITAGE PHARMA	EQ 4MG BASE	A077587	001	Jul 09, 2009	Sep	DISC	
>A>		@	EQ 4MG BASE	A077587	001	Jul 09, 2009	Sep	DISC	
>D>	AB		EQ 8MG BASE	A077587	002	Jul 09, 2009	Sep	DISC	
>A>		@	EQ 8MG BASE	A077587	002	Jul 09, 2009	Sep	DISC	
>D>	AB		EQ 12MG BASE	A077587	003	Jul 09, 2009	Sep	DISC	
>A>		@	EQ 12MG BASE	A077587	003	Jul 09, 2009	Sep	DISC	
		GANCICLOVIR							
		SOLUTION;INTRAVENOUS							
>D>		GANCICLOVIR							
>D>		+! EXELA PHARMA SCS LLC	500MG/250ML (2MG/ML)	N209347	001	Feb 17, 2017	Sep	CTNA	
>A>		GANZYK-RTU							
>A>		+! EXELA PHARMA SCS LLC	500MG/250ML (2MG/ML)	N209347	001	Feb 17, 2017	Sep	CTNA	
		GEMCITABINE HYDROCHLORIDE							
		INJECTABLE;INJECTION							
		GEMCITABINE HYDROCHLORIDE							
>A>	AP	SHILPA MEDICARE LTD	200MG/5.26ML (38MG/ML)	A210991	001	Oct 04, 2019	Sep	NEWA	
>A>	AP		1GM/26.3ML (38MG/ML)	A210991	002	Oct 04, 2019	Sep	NEWA	
>A>	AP		2GM/52.6ML (38MG/ML)	A210991	003	Oct 04, 2019	Sep	NEWA	
		GENTAMICIN SULFATE							
		OINTMENT;OPHTHALMIC							
		GENTAMICIN SULFATE							
>A>	AT	FERA PHARMS LLC	EQ 0.3% BASE	A065024	001	Jul 30, 2004	Sep	CAHN	
>D>	AT	PERRIGO CO TENNESSEE	EQ 0.3% BASE	A065024	001	Jul 30, 2004	Sep	CAHN	
		GLUCAGON							
>A>		SOLUTION;SUBCUTANEOUS							
>A>		GVOKE HYPOPEN							
>A>		+! XERIS	0.5MG/0.1ML (0.5MG/0.1ML)	N212097	003	Sep 10, 2019	Sep	NEWA	
>A>		+!	1MG/0.2ML (1MG/0.2ML)	N212097	004	Sep 10, 2019	Sep	NEWA	
>A>		GVOKE PFS							
>A>		+! XERIS	0.5MG/0.1ML (0.5MG/0.1ML)	N212097	001	Sep 10, 2019	Sep	NEWA	
>A>		+!	1MG/0.2ML (1MG/0.2ML)	N212097	002	Sep 10, 2019	Sep	NEWA	

GLYCOPYRROLATE
INJECTABLE;INJECTION
GLYCOPYRROLATE

>A>	AP	GLAND PHARMA LTD	0.2MG/ML	A212612	001	Sep 30, 2019	Sep	NEWA	

HALOBETASOL PROPIONATE
AEROSOL, FOAM;TOPICAL

>D>		HALOBETASOL PROPIONATE							
>D>	+!	MAYNE PHARMA	0.05%	N210566	001	May 24, 2018	Sep	CTNA	
>A>		LEXETTE							
>A>	+!	MAYNE PHARMA	0.05%	N210566	001	May 24, 2018	Sep	CTNA	

HALOPERIDOL LACTATE
CONCENTRATE;ORAL
HALOPERIDOL INTENSOL

>D>		@ CYCLE PHARMS LTD	EQ 2MG BASE/ML	A072045	001	Apr 12, 1988	Sep	CAHN	
>A>		@ HIKMA	EQ 2MG BASE/ML	A072045	001	Apr 12, 1988	Sep	CAHN	

HYDROCHLOROTHIAZIDE; OLMESARTAN MEDOXOMIL
TABLET;ORAL
OLMESARTAN MEDOXOMIL AND HYDROCHLOROTHIAZIDE

>A>	AB	UMEDICA LABS PVT LTD	12.5MG;20MG	A208847	001	Sep 17, 2019	Sep	NEWA	
>A>	AB		12.5MG;40MG	A208847	003	Sep 17, 2019	Sep	NEWA	
>A>	AB		25MG;40MG	A208847	002	Sep 17, 2019	Sep	NEWA	

HYDROXYCHLOROQUINE SULFATE
TABLET;ORAL
HYDROXYCHLOROQUINE SULFATE

>D>	AB	LAURUS LABS LTD	200MG	A210959	001	Jan 15, 2019	Sep	DISC	
>A>		@	200MG	A210959	001	Jan 15, 2019	Sep	DISC	

HYDROXYZINE HYDROCHLORIDE
SYRUP;ORAL
HYDROXYZINE HYDROCHLORIDE

>A>		@ ANIMA	10MG/5ML	A086880	001	Jul 17, 1980	Sep	CAHN	
>D>		@ STI PHARMA LLC	10MG/5ML	A086880	001	Jul 17, 1980	Sep	CAHN	

IFOSFAMIDE
INJECTABLE;INJECTION
IFOSFAMIDE

>D>	AP	MYLAN LABS LTD	1GM/20ML (50MG/ML)	A201689	001	Nov 26, 2012	Sep	DISC	
>A>		@	1GM/20ML (50MG/ML)	A201689	001	Nov 26, 2012	Sep	DISC	
>D>	AP		3GM/60ML (50MG/ML)	A201689	002	Nov 26, 2012	Sep	DISC	
>A>		@	3GM/60ML (50MG/ML)	A201689	002	Nov 26, 2012	Sep	DISC	

INDOMETHACIN
SUSPENSION;ORAL
INDOMETHACIN

>D>		@ CYCLE PHARMS LTD	25MG/5ML	A071412	001	Mar 18, 1987	Sep	CAHN	
>A>		@ HIKMA	25MG/5ML	A071412	001	Mar 18, 1987	Sep	CAHN	

IRINOTECAN HYDROCHLORIDE
INJECTABLE;INJECTION
IRINOTECAN HYDROCHLORIDE

>D>	AP	MUSTAFA NEVZAT ILAC	40MG/2ML (20MG/ML)	A090393	002	May 13, 2011	Sep	CAHN	
>D>	AP		100MG/5ML (20MG/ML)	A090393	003	May 13, 2011	Sep	CAHN	
>A>	AP	ZENNOVA	40MG/2ML (20MG/ML)	A090393	002	May 13, 2011	Sep	CAHN	
>A>	AP		100MG/5ML (20MG/ML)	A090393	003	May 13, 2011	Sep	CAHN	

ISOSULFAN BLUE
INJECTABLE;INJECTION
ISOSULFAN BLUE

>A>	AP	ANDA REPOSITORY	1%	A210558	001	Jul 12, 2019	Sep	CAHN	
>D>	AP	SOMERSET THERAPS LLC	1%	A210558	001	Jul 12, 2019	Sep	CAHN	

IVERMECTIN
CREAM;TOPICAL

>A>		IVERMECTIN							
>A>	AB	TEVA PHARMS USA	1%	A210019	001	Sep 13, 2019	Sep	NFTG	
		SOOLANTRA							
>D>	+!	GALDERMA LABS LP	1%	N206255	001	Dec 19, 2014	Sep	CFTG	

IVERMECTIN
CREAM;TOPICAL
SOOLANTRA

>A>	AB	+!	1%		N206255	001	Dec 19, 2014	Sep	CFTG

LABETALOL HYDROCHLORIDE
INJECTABLE;INJECTION
LABETALOL HYDROCHLORIDE

>D>	AP	MYLAN ASI	5MG/ML		A079134	001	Feb 03, 2010	Sep	DISC
>A>		@	5MG/ML		A079134	001	Feb 03, 2010	Sep	DISC

LAMIVUDINE; ZIDOVUDINE
TABLET;ORAL
LAMIVUDINE AND ZIDOVUDINE

>A>	AB	ANDA REPOSITORY	150MG;300MG		A206375	001	Apr 10, 2018	Sep	CAHN
>D>	AB	SHANGHAI DESANO	150MG;300MG		A206375	001	Apr 10, 2018	Sep	CAHN

LANSOPRAZOLE
CAPSULE, DELAYED REL PELLETS;ORAL
LANSOPRAZOLE

>D>	AB	AJANTA PHARMA LTD	15MG		A203957	001	Oct 14, 2016	Sep	DISC
>A>		@	15MG		A203957	001	Oct 14, 2016	Sep	DISC
>D>	AB		30MG		A203957	002	Oct 14, 2016	Sep	DISC
>A>		@	30MG		A203957	002	Oct 14, 2016	Sep	DISC

LETROZOLE
TABLET;ORAL
LETROZOLE

>D>		@ EUGIA PHARMA	2.5MG		A211717	001	Jan 11, 2019	Sep	CMFD
>A>	AB		2.5MG		A211717	001	Jan 11, 2019	Sep	CMFD

LEVETIRACETAM
TABLET, EXTENDED RELEASE;ORAL
LEVETIRACETAM

>A>	AB	ANDA REPOSITORY	500MG		A204511	001	Feb 23, 2016	Sep	CAHN
>A>	AB		750MG		A204511	002	Feb 23, 2016	Sep	CAHN
>A>	AB	HISUN PHARM HANGZHOU	500MG		A207175	001	Sep 28, 2017	Sep	CAHN
>A>	AB		750MG		A207175	002	Sep 28, 2017	Sep	CAHN
>D>	AB	INTELLIPHARMACEUTICS	500MG		A204511	001	Feb 23, 2016	Sep	CAHN
>D>	AB		750MG		A204511	002	Feb 23, 2016	Sep	CAHN
>D>	AB	PHARMTAK INC	500MG		A207175	001	Sep 28, 2017	Sep	CAHN
>D>	AB		750MG		A207175	002	Sep 28, 2017	Sep	CAHN

LEVOTHYROXINE SODIUM
TABLET;ORAL
LEVOTHYROXINE SODIUM

>D>	AB2	LUPIN ATLANTIS	0.025MG		A209713	001	Jan 18, 2019	Sep	CTEC
>A>	-->		--> AB1,AB2	0.025MG	A209713	001	Jan 18, 2019	Sep	CTEC
>D>	AB2		0.05MG		A209713	002	Jan 18, 2019	Sep	CTEC
>A>	-->		--> AB1,AB2	0.05MG	A209713	002	Jan 18, 2019	Sep	CTEC
>D>	AB2		0.075MG		A209713	003	Jan 18, 2019	Sep	CTEC
>A>	-->		--> AB1,AB2	0.075MG	A209713	003	Jan 18, 2019	Sep	CTEC
>D>	AB2		0.088MG		A209713	004	Jan 18, 2019	Sep	CTEC
>A>	-->		--> AB1,AB2	0.088MG	A209713	004	Jan 18, 2019	Sep	CTEC
>D>	AB2		0.1MG		A209713	005	Jan 18, 2019	Sep	CTEC
>A>	-->		--> AB1,AB2	0.1MG	A209713	005	Jan 18, 2019	Sep	CTEC
>D>	AB2		0.112MG		A209713	006	Jan 18, 2019	Sep	CTEC
>A>	-->		--> AB1,AB2	0.112MG	A209713	006	Jan 18, 2019	Sep	CTEC
>D>	AB2		0.125MG		A209713	007	Jan 18, 2019	Sep	CTEC
>A>	-->		--> AB1,AB2	0.125MG	A209713	007	Jan 18, 2019	Sep	CTEC
>D>	AB2		0.137MG		A209713	008	Jan 18, 2019	Sep	CTEC
>A>	-->		--> AB1,AB2	0.137MG	A209713	008	Jan 18, 2019	Sep	CTEC
>D>	AB2		0.15MG		A209713	009	Jan 18, 2019	Sep	CTEC
>A>	-->		--> AB1,	0.15MG	A209713	009	Jan 18, 2019	Sep	CTEC

ADDITIONS/DELETIONS FOR PRESCRIPTION DRUG PRODUCT LIST

LEVOTHYROXINE SODIUM
TABLET;ORAL
LEVOTHYROXINE SODIUM

			AB2						
>D>	AB2		0.175MG		A209713	010	Jan 18, 2019	Sep	CTEC
>A>	-->		--> AB1,AB2	0.175MG	A209713	010	Jan 18, 2019	Sep	CTEC
>D>	AB2		0.2MG		A209713	011	Jan 18, 2019	Sep	CTEC
>A>	-->		--> AB1,AB2	0.2MG	A209713	011	Jan 18, 2019	Sep	CTEC
>D>	AB2		0.3MG		A209713	012	Jan 18, 2019	Sep	CTEC
>A>	-->		--> AB1,AB2	0.3MG	A209713	012	Jan 18, 2019	Sep	CTEC

LIDOCAINE
OINTMENT;TOPICAL
LIDOCAINE

>A>	AT	NOVAST LABS	5%		A208604	001	Sep 20, 2017	Sep	CAHN
>D>	AT	RICONPHARMA LLC	5%		A208604	001	Sep 20, 2017	Sep	CAHN

LIDOCAINE HYDROCHLORIDE
INJECTABLE;INJECTION
LIDOCAINE HYDROCHLORIDE

>D>	AP	HOSPIRA	1%		A083158	001	Oct 31, 1972	Sep	CHRS
>A>	AP	!	1%		A083158	001	Oct 31, 1972	Sep	CHRS
>D>	AP		2%		A083158	002	Oct 31, 1972	Sep	CHRS
>A>	AP	!	2%		A083158	002	Oct 31, 1972	Sep	CHRS
>D>	AP		20%		A083158	003	Feb 11, 1977	Sep	DISC
>A>		@	20%		A083158	003	Feb 11, 1977	Sep	DISC
>D>		XYLOCAINE PRESERVATIVE FREE							
>D>	AP	+! FRESENIUS KABI USA	1%		N016801	005	Jan 19, 1988	Sep	DISC
>A>		+ @	1%		N016801	005	Jan 19, 1988	Sep	DISC
>D>	AP	+!	2%		N016801	001	Oct 06, 1969	Sep	DISC
>A>		+ @	2%		N016801	001	Oct 06, 1969	Sep	DISC
>D>	AP	+!	4%		N016801	002	Apr 13, 1976	Sep	DISC
>A>		+ @	4%		N016801	002	Apr 13, 1976	Sep	DISC
>D>	AP	+!	20%		N016801	004	Sep 29, 1978	Sep	DISC
>A>		+ @	20%		N016801	004	Sep 29, 1978	Sep	DISC

SOLUTION;TOPICAL
LIDOCAINE HYDROCHLORIDE

>D>		@ LANNETT CO INC	4%		A040710	001	Feb 27, 2007	Sep	CMFD
>A>	AT		4%		A040710	001	Feb 27, 2007	Sep	CMFD

LIFITEGRAST
SOLUTION/DROPS;OPHTHALMIC
XIIDRA

>A>		+! NOVARTIS	5%		N208073	001	Jul 11, 2016	Sep	CAHN
>D>		+! SHIRE DEV LLC	5%		N208073	001	Jul 11, 2016	Sep	CAHN

LURASIDONE HYDROCHLORIDE
TABLET;ORAL
LURASIDONE HYDROCHLORIDE

>D>	AB	EMCURE PHARMS LTD	20MG		A208058	001	Sep 04, 2019	Sep	DISC
>A>		@	20MG		A208058	001	Sep 04, 2019	Sep	DISC
>D>	AB		40MG		A208058	002	Sep 04, 2019	Sep	DISC
>A>		@	40MG		A208058	002	Sep 04, 2019	Sep	DISC
>D>	AB		60MG		A208058	003	Sep 04, 2019	Sep	DISC
>A>		@	60MG		A208058	003	Sep 04, 2019	Sep	DISC
>D>	AB		80MG		A208058	004	Sep 04, 2019	Sep	DISC
>A>		@	80MG		A208058	004	Sep 04, 2019	Sep	DISC

MECLIZINE HYDROCHLORIDE
TABLET;ORAL
MECLIZINE HYDROCHLORIDE

>A>		@ ANI PHARMS INC	12.5MG		A084657	002	Mar 18, 1976	Sep	CMS1

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MELOXICAM
TABLET;ORAL
MELOXICAM

>D>	AB		HERITAGE PHARMA	7.5MG	A077936	001	Jul 19, 2006	Sep	DISC
>A>		@		7.5MG	A077936	001	Jul 19, 2006	Sep	DISC
>D>	AB			15MG	A077936	002	Jul 19, 2006	Sep	DISC
>A>		@		15MG	A077936	002	Jul 19, 2006	Sep	DISC

MELPHALAN HYDROCHLORIDE
INJECTABLE;INJECTION
MELPHALAN HYDROCHLORIDE

>A>	AP		NORATECH	EQ 50MG BASE/VIAL	A211463	001	Sep 13, 2019	Sep	NEWA

MEROPENEM
INJECTABLE;INJECTION
MEROPENEM

>D>	AP		HOSPIRA INC	500MG/VIAL	A090940	001	Jun 22, 2010	Sep	DISC
>A>		@		500MG/VIAL	A090940	001	Jun 22, 2010	Sep	DISC
>D>	AP			1GM/VIAL	A090940	002	Jun 22, 2010	Sep	DISC
>A>		@		1GM/VIAL	A090940	002	Jun 22, 2010	Sep	DISC

METFORMIN HYDROCHLORIDE
TABLET, EXTENDED RELEASE;ORAL
METFORMIN HYDROCHLORIDE

>D>	AB1	!	SUN PHARM INDS (IN)	500MG	A077336	001	Feb 09, 2006	Sep	CHRS
>A>	AB1			500MG	A077336	001	Feb 09, 2006	Sep	CHRS

METHADONE HYDROCHLORIDE
SOLUTION;ORAL
METHADONE HYDROCHLORIDE

>A>	AA		PHARM ASSOC	5MG/5ML	A207537	001	Oct 02, 2019	Sep	NEWA
>A>	AA			10MG/5ML	A207537	002	Oct 01, 2019	Sep	NEWA

METHOCARBAMOL
TABLET;ORAL
METHOCARBAMOL

>A>	AA		ANI PHARMS INC	500MG	A084277	001	Mar 14, 1977	Sep	CAHN
>D>	AA		WATSON LABS	500MG	A084277	001	Mar 14, 1977	Sep	CAHN

METHYLPHENIDATE HYDROCHLORIDE
SOLUTION;ORAL
METHYLPHENIDATE HYDROCHLORIDE

>A>	AA		NOVELGENIX THERAPS	5MG/5ML	A210139	001	Oct 03, 2018	Sep	CAHN
>A>	AA			10MG/5ML	A210139	002	Oct 03, 2018	Sep	CAHN
>D>	AA		WES PHARMA INC	5MG/5ML	A210139	001	Oct 03, 2018	Sep	CAHN
>D>	AA			10MG/5ML	A210139	002	Oct 03, 2018	Sep	CAHN

TABLET;ORAL
METHYLPHENIDATE HYDROCHLORIDE

>A>	AB		ALKEM LABS LTD	5MG	A211779	001	Oct 04, 2019	Sep	NEWA
>A>	AB			10MG	A211779	002	Oct 04, 2019	Sep	NEWA
>A>	AB			20MG	A211779	003	Oct 04, 2019	Sep	NEWA

METHYLPREDNISOLONE
TABLET;ORAL
METHYLPREDNISOLONE

>D>	AB		LUPIN LTD	2MG	A209097	001	Feb 22, 2019	Sep	DISC
>A>		@		2MG	A209097	001	Feb 22, 2019	Sep	DISC
>D>	AB			4MG	A209097	002	Feb 22, 2019	Sep	DISC
>A>		@		4MG	A209097	002	Feb 22, 2019	Sep	DISC
>D>	AB			8MG	A209097	003	Feb 22, 2019	Sep	DISC
>A>		@		8MG	A209097	003	Feb 22, 2019	Sep	DISC
>D>	AB			16MG	A209097	004	Feb 22, 2019	Sep	DISC
>A>		@		16MG	A209097	004	Feb 22, 2019	Sep	DISC
>D>	AB			32MG	A209097	005	Feb 22, 2019	Sep	DISC
>A>		@		32MG	A209097	005	Feb 22, 2019	Sep	DISC
>A>	AB		NOVAST LABS	4MG	A210985	001	Jan 09, 2019	Sep	CAHN
>D>	AB		RICONPHARMA LLC	4MG	A210985	001	Jan 09, 2019	Sep	CAHN

		METOLAZONE						
		TABLET;ORAL						
		METOLAZONE						
>A>		@ ANI PHARMS INC	5MG	A076833	001	Mar 01, 2004	Sep	CAHN
>A>		@	10MG	A075543	003	Dec 24, 2003	Sep	CAHN
>D>		@ TEVA	5MG	A076833	001	Mar 01, 2004	Sep	CAHN
>D>		@	10MG	A075543	003	Dec 24, 2003	Sep	CAHN
		MIDAZOLAM HYDROCHLORIDE						
		INJECTABLE;INJECTION						
		MIDOZALAM HYDROCHLORIDE						
>D>	AP	MYLAN ASI	EQ 1MG BASE/ML	A090316	001	May 04, 2011	Sep	DISC
>A>		@	EQ 1MG BASE/ML	A090316	001	May 04, 2011	Sep	DISC
>D>	AP		EQ 5MG BASE/ML	A090316	002	May 04, 2011	Sep	DISC
>A>		@	EQ 5MG BASE/ML	A090316	002	May 04, 2011	Sep	DISC
		MITOXANTRONE HYDROCHLORIDE						
		INJECTABLE;INJECTION						
		MITOXANTRONE HYDROCHLORIDE						
>D>	AP	MYLAN LABS LTD	EQ 20MG BASE/10ML (EQ 2MG BASE/ML)	A201014	001	Dec 11, 2012	Sep	DISC
>A>		@	EQ 20MG BASE/10ML (EQ 2MG BASE/ML)	A201014	001	Dec 11, 2012	Sep	DISC
		NOVANTRONE						
>D>		@ EMD SERONO	EQ 20MG BASE/10ML (EQ 2MG BASE/ML)	N019297	001	Dec 23, 1987	Sep	CRLD
>A>		+ @	EQ 20MG BASE/10ML (EQ 2MG BASE/ML)	N019297	001	Dec 23, 1987	Sep	CRLD
		MORPHINE SULFATE						
		INJECTABLE;INJECTION						
		MORPHINE SULFATE						
>D>		+! ICU MEDICAL INC	5MG/ML	N019916	002	Oct 27, 2006	Sep	DISC
>A>		+ @	5MG/ML	N019916	002	Oct 27, 2006	Sep	DISC
		MYCOPHENOLATE MOFETIL						
		TABLET;ORAL						
		MYCOPHENOLATE MOFETIL						
>D>	AB	TEVA PHARMS	500MG	A065457	001	May 04, 2009	Sep	DISC
>A>		@	500MG	A065457	001	May 04, 2009	Sep	DISC
		NABUMETONE						
		TABLET;ORAL						
		NABUMETONE						
>D>		@ SCIEGEN PHARMS INC	500MG	A078420	001	Sep 24, 2008	Sep	CMFD
>A>	AB		500MG	A078420	001	Sep 24, 2008	Sep	CMFD
>D>		@	750MG	A078420	002	Sep 24, 2008	Sep	CMFD
>A>	AB		750MG	A078420	002	Sep 24, 2008	Sep	CMFD
		NADOLOL						
		TABLET;ORAL						
		NADOLOL						
>A>	AB	VGYAAN	20MG	A212856	001	Sep 13, 2019	Sep	NEWA
>A>	AB		40MG	A212856	002	Sep 13, 2019	Sep	NEWA
>A>	AB		80MG	A212856	003	Sep 13, 2019	Sep	NEWA
		NAFCILLIN SODIUM						
		INJECTABLE;INJECTION						
		NAFCILLIN SODIUM						
>D>	AP	MYLAN LABS LTD	EQ 1GM BASE/VIAL	A200002	001	Apr 07, 2014	Sep	DISC
>A>		@	EQ 1GM BASE/VIAL	A200002	001	Apr 07, 2014	Sep	DISC
>D>	AP		EQ 2GM BASE/VIAL	A200002	002	Apr 07, 2014	Sep	DISC
>A>		@	EQ 2GM BASE/VIAL	A200002	002	Apr 07, 2014	Sep	DISC
		NALOXONE HYDROCHLORIDE						
		INJECTABLE;INJECTION						
		NALOXONE HYDROCHLORIDE						
>A>	AP	AUROBINDO PHARMA LTD	0.4MG/ML	A212455	001	Oct 15, 2019	Sep	NEWA

NARATRIPTAN HYDROCHLORIDE
TABLET;ORAL
NARATRIPTAN

>A>	AB	ANI PHARMS INC	EQ 1MG BASE	A078751	001	Jul 07, 2010	Sep	CAHN
>A>	AB		EQ 2.5MG BASE	A078751	002	Jul 07, 2010	Sep	CAHN
>D>	AB	TEVA PHARMS	EQ 1MG BASE	A078751	001	Jul 07, 2010	Sep	CAHN
>D>	AB		EQ 2.5MG BASE	A078751	002	Jul 07, 2010	Sep	CAHN

>D> NEBIVOLOL HYDROCHLORIDE; VALSARTAN
>D> TABLET;ORAL
>D> BYVALSON

>D>	+!	ALLERGAN SALES LLC	EQ 5MG BASE;80MG	N206302	001	Jun 03, 2016	Sep	DISC
>A>	+ @		EQ 5MG BASE;80MG	N206302	001	Jun 03, 2016	Sep	DISC

NEOSTIGMINE METHYLSULFATE
SOLUTION;INTRAVENOUS
NEOSTIGMINE METHYLSULFATE

>A>	AP	GLAND PHARMA LTD	5MG/10ML (0.5MG/ML)	A212968	001	Oct 16, 2019	Sep	NEWA
>A>	AP		10MG/10ML (1MG/ML)	A212968	002	Oct 16, 2019	Sep	NEWA

NIACIN
TABLET, EXTENDED RELEASE;ORAL
NIACIN

>D>		@ JUBILANT GENERICS	500MG	A209156	001	May 14, 2018	Sep	CMFD
>A>	AB		500MG	A209156	001	May 14, 2018	Sep	CMFD
>D>		@	750MG	A209156	002	May 14, 2018	Sep	CMFD
>A>	AB		750MG	A209156	002	May 14, 2018	Sep	CMFD
>D>		@	1GM	A209156	003	May 14, 2018	Sep	CMFD
>A>	AB		1GM	A209156	003	May 14, 2018	Sep	CMFD

NICARDIPINE HYDROCHLORIDE
CAPSULE;ORAL
NICARDIPINE HYDROCHLORIDE

>A>		@ ANI PHARMS INC	20MG	A074670	001	Oct 28, 1996	Sep	CAHN
>A>		@	30MG	A074670	002	Oct 28, 1996	Sep	CAHN
>D>		@ WATSON LABS	20MG	A074670	001	Oct 28, 1996	Sep	CAHN
>D>		@	30MG	A074670	002	Oct 28, 1996	Sep	CAHN

NORETHINDRONE ACETATE
TABLET;ORAL
NORETHINDRONE ACETATE

>D>	AB	AUROBINDO PHARMA LTD	5MG	A204236	001	Jan 08, 2016	Sep	DISC
>A>		@	5MG	A204236	001	Jan 08, 2016	Sep	DISC

NYSTATIN; TRIAMCINOLONE ACETONIDE
OINTMENT;TOPICAL
NYSTATIN AND TRIAMCINOLONE ACETONIDE

>D>	AT	CROWN LABS INC	100,000 UNITS/GM;0.1%	A207731	001	Dec 26, 2017	Sep	DISC
>A>		@	100,000 UNITS/GM;0.1%	A207731	001	Dec 26, 2017	Sep	DISC

OFLOXACIN
TABLET;ORAL
OFLOXACIN

>D>	AB	LARKEN LABS	400MG	A076093	003	Sep 02, 2003	Sep	DISC
>A>		@	400MG	A076093	003	Sep 02, 2003	Sep	DISC

OLMESARTAN MEDOXOMIL
TABLET;ORAL
OLMESARTAN MEDOXOMIL

>A>	AB	MICRO LABS	5MG	A206372	001	Sep 17, 2019	Sep	NEWA
>A>	AB		20MG	A206372	002	Sep 17, 2019	Sep	NEWA
>A>	AB		40MG	A206372	003	Sep 17, 2019	Sep	NEWA

OLOPATADINE HYDROCHLORIDE
SOLUTION/DROPS;OPHTHALMIC
OLOPATADINE HYDROCHLORIDE

>A>	AT	FDC LTD	EQ 0.1% BASE	A209282	001	Sep 26, 2019	Sep	NEWA

OMEPRAZOLE
CAPSULE, DELAYED REL PELLETS;ORAL
OMEPRAZOLE

>A>	AB		HETERO LABS LTD III	10MG	A204012	001	Sep 26, 2019	Sep	NEWA
>A>	AB			20MG	A204012	002	Sep 26, 2019	Sep	NEWA
>D>	AB		MYLAN	40MG	A075876	003	Jan 21, 2009	Sep	DISC
>A>			@	40MG	A075876	003	Jan 21, 2009	Sep	DISC

OMEPRAZOLE; SODIUM BICARBONATE
CAPSULE;ORAL
ZEGERID

>A>	AB	+	SALIX	20MG;1.1GM	N021849	001	Feb 27, 2006	Sep	CAHN
>A>	AB	+!		40MG;1.1GM	N021849	002	Feb 27, 2006	Sep	CAHN
>D>	AB	+	SANTARUS INC	20MG;1.1GM	N021849	001	Feb 27, 2006	Sep	CAHN
>D>	AB	+!		40MG;1.1GM	N021849	002	Feb 27, 2006	Sep	CAHN

OXALIPLATIN
INJECTABLE;INTRAVENOUS
OXALIPLATIN

>D>	AP		MYLAN LABS LTD	200MG/40ML (5MG/ML)	A091358	003	Nov 14, 2017	Sep	DISC
>A>			@	200MG/40ML (5MG/ML)	A091358	003	Nov 14, 2017	Sep	DISC

OXYBUTYNIN CHLORIDE
SYRUP;ORAL
OXYBUTYNIN CHLORIDE

>D>	AA		LANNETT CO INC	5MG/5ML	A076682	001	Dec 28, 2004	Sep	DISC
>A>			@	5MG/5ML	A076682	001	Dec 28, 2004	Sep	DISC

TABLET;ORAL
OXYBUTYNIN CHLORIDE

>D>	AB		APPCO PHARMA LLC	5MG	A209025	001	Dec 21, 2017	Sep	CAHN
>A>	AB		ARISE	5MG	A209025	001	Dec 21, 2017	Sep	CAHN

OXYCODONE HYDROCHLORIDE
SOLUTION;ORAL
OXYCODONE HYDROCHLORIDE

>A>	AA		EYWA	5MG/5ML	A207511	001	Nov 23, 2016	Sep	CAHN
>A>	AA			100MG/5ML	A209897	001	Sep 06, 2017	Sep	CAHN
>D>	AA		WES PHARMA INC	5MG/5ML	A207511	001	Nov 23, 2016	Sep	CAHN
>D>	AA			100MG/5ML	A209897	001	Sep 06, 2017	Sep	CAHN

TABLET;ORAL
ROXYBOND

>D>			@ DAIICHI SANKYO INC	5MG	N209777	001	Apr 20, 2017	Sep	CAHN
>D>			@	15MG	N209777	002	Apr 20, 2017	Sep	CAHN
>D>			@	30MG	N209777	003	Apr 20, 2017	Sep	CAHN
>A>			@ INSPIRION DELIVERY	5MG	N209777	001	Apr 20, 2017	Sep	CAHN
>A>			@	15MG	N209777	002	Apr 20, 2017	Sep	CAHN
>A>			@	30MG	N209777	003	Apr 20, 2017	Sep	CAHN

PACLITAXEL
INJECTABLE;INJECTION
TAXOL

>D>									
>D>	AP	+	HQ SPCLT PHARMA	6MG/ML	N020262	001	Dec 29, 1992	Sep	DISC
>A>		+ @		6MG/ML	N020262	001	Dec 29, 1992	Sep	DISC

PALIPERIDONE
TABLET, EXTENDED RELEASE;ORAL
PALIPERIDONE

>A>	AB		AMNEAL PHARMS	1.5MG	A204707	001	Sep 23, 2019	Sep	NEWA
>A>	AB			3MG	A204707	002	Sep 23, 2019	Sep	NEWA
>A>	AB			6MG	A204707	003	Sep 23, 2019	Sep	NEWA
>A>	AB			9MG	A204707	004	Sep 23, 2019	Sep	NEWA

PANTOPRAZOLE SODIUM
POWDER;IV (INFUSION)
PANTOPRAZOLE SODIUM

>D>			HIKMA	EQ 40MG BASE/VIAL	N209463	001	Jun 30, 2017	Sep	CHRS
>A>		!		EQ 40MG BASE/VIAL	N209463	001	Jun 30, 2017	Sep	CHRS
>A>		+!		EQ 40MG BASE/VIAL	N209463	001	Jun 30, 2017	Sep	CRLD

		PENTOBARBITAL SODIUM							
		INJECTABLE;INJECTION							
		PENTOBARBITAL SODIUM							
>A>	AP	ATHENEX	50MG/ML	A206677	001	Nov 27, 2017	Sep	CAHN	
>D>	AP	RENAISSANCE SSA LLC	50MG/ML	A206677	001	Nov 27, 2017	Sep	CAHN	
		PENTOXIFYLLINE							
		TABLET, EXTENDED RELEASE;ORAL							
		PENTOXIFYLLINE							
>A>		@ ANI PHARMS INC	400MG	A075107	001	Sep 04, 1998	Sep	CAHN	
>D>		@ WATSON LABS	400MG	A075107	001	Sep 04, 1998	Sep	CAHN	
		PHENYTOIN SODIUM							
		CAPSULE;ORAL							
		EXTENDED PHENYTOIN SODIUM							
>A>	AB	LUPIN LTD	100MG EXTENDED	A211633	001	Sep 30, 2019	Sep	NEWA	
		PIMOZIDE							
		TABLET;ORAL							
>D>		ORAP							
>D>	AB	+ TEVA	1MG	N017473	003	Aug 27, 1997	Sep	DISC	
>A>		+ @	1MG	N017473	003	Aug 27, 1997	Sep	DISC	
>D>	AB	+!	2MG	N017473	001	Jul 31, 1984	Sep	DISC	
>A>		+ @	2MG	N017473	001	Jul 31, 1984	Sep	DISC	
		PIMOZIDE							
>D>	AB	PAR PHARM	1MG	A204521	001	Sep 28, 2015	Sep	CTEC	
>A>			1MG	A204521	001	Sep 28, 2015	Sep	CTEC	
>D>	AB		2MG	A204521	002	Sep 28, 2015	Sep	CTEC	
>A>		!	2MG	A204521	002	Sep 28, 2015	Sep	CHRS	
>A>			2MG	A204521	002	Sep 28, 2015	Sep	CTEC	
		PITAVASTATIN MAGNESIUM							
		TABLET;ORAL							
		ZYPITAMAG							
>A>		+ @ MEDICURE	EQ 1MG BASE	N208379	001	Jul 14, 2017	Sep	DISC	
>D>		+ ZYDUS PHARMS	EQ 1MG BASE	N208379	001	Jul 14, 2017	Sep	DISC	
		PITOLISANT HYDROCHLORIDE							
		TABLET;ORAL							
		WAKIX							
>D>		+ BIOPROJET PHARMA	EQ 4.45MG BASE	N211150	001	Aug 14, 2019	Sep	CAHN	
>D>		+!	EQ 17.8MG BASE	N211150	002	Aug 14, 2019	Sep	CAHN	
>A>		+ HARMONY	EQ 4.45MG BASE	N211150	001	Aug 14, 2019	Sep	CAHN	
>A>		+!	EQ 17.8MG BASE	N211150	002	Aug 14, 2019	Sep	CAHN	
		POTASSIUM CHLORIDE							
		TABLET, EXTENDED RELEASE;ORAL							
		K-TAB							
>D>	AB2	+! ABBVIE	20MEQ	N018279	003	Nov 25, 2013	Sep	CTEC	
>A>	AB3	+!	20MEQ	N018279	003	Nov 25, 2013	Sep	CTEC	
		POTASSIUM CHLORIDE							
>D>	AB2	BRECKENRIDGE	20MEQ	A210098	001	Apr 26, 2019	Sep	CTEC	
>A>	AB3		20MEQ	A210098	001	Apr 26, 2019	Sep	CTEC	
>D>	AB2	VITRUVIAS THERAP	20MEQ	A209688	002	Jan 12, 2018	Sep	CTEC	
>A>	AB3		20MEQ	A209688	002	Jan 12, 2018	Sep	CTEC	
>A>	AB3	YICHANG HUMANWELL	10MEQ	A212561	001	Sep 30, 2019	Sep	NEWA	
>A>	AB3		20MEQ	A212561	002	Sep 30, 2019	Sep	NEWA	
>A>		POTASSIUM PHOSPHATE, DIBASIC; POTASSIUM PHOSPHATE, MONOBASIC							
>A>		SOLUTION;INTRAVENOUS							
>A>		POTASSIUM PHOSPHATES							
>A>		+! CMP DEV LLC	4500MG/15ML (300MG/ML); 2650MG/15ML (175MG/ML)	N212121	001	Sep 19, 2019	Sep	NEWA	
		PRAMIPEXOLE DIHYDROCHLORIDE							
		TABLET;ORAL							
		PRAMIPEXOLE DIHYDROCHLORIDE							
>A>	AB	HERITAGE PHARMA	0.125MG	A090241	001	Oct 08, 2010	Sep	CAHN	
>A>	AB		0.25MG	A090241	002	Oct 08, 2010	Sep	CAHN	
>A>	AB		0.5MG	A090241	003	Oct 08, 2010	Sep	CAHN	
>A>	AB		0.75MG	A090241	004	Oct 08, 2010	Sep	CAHN	

PRAMIPEXOLE DIHYDROCHLORIDE
TABLET;ORAL
PRAMIPEXOLE DIHYDROCHLORIDE

>A>	AB		1MG	A090241	005	Oct 08, 2010	Sep	CAHN
>A>	AB		1.5MG	A090241	006	Oct 08, 2010	Sep	CAHN
>D>	AB	TEVA PHARMS	0.125MG	A090241	001	Oct 08, 2010	Sep	CAHN
>D>	AB		0.25MG	A090241	002	Oct 08, 2010	Sep	CAHN
>D>	AB		0.5MG	A090241	003	Oct 08, 2010	Sep	CAHN
>D>	AB		0.75MG	A090241	004	Oct 08, 2010	Sep	CAHN
>D>	AB		1MG	A090241	005	Oct 08, 2010	Sep	CAHN
>D>	AB		1.5MG	A090241	006	Oct 08, 2010	Sep	CAHN

PREGABALIN
CAPSULE;ORAL
PREGABALIN

>A>	AB	ALKEM LABS LTD	25MG	A211177	001	Sep 30, 2019	Sep	NEWA
>A>	AB		50MG	A211177	002	Sep 30, 2019	Sep	NEWA
>A>	AB	HAINAN	75MG	A210891	001	Sep 30, 2019	Sep	NEWA
>A>	AB		300MG	A210891	002	Sep 30, 2019	Sep	NEWA
>A>	AB	HETERO LABS LTD III	25MG	A206912	001	Oct 08, 2019	Sep	NEWA
>A>	AB		50MG	A206912	002	Oct 08, 2019	Sep	NEWA
>A>	AB		75MG	A206912	003	Oct 08, 2019	Sep	NEWA
>A>	AB		100MG	A206912	004	Oct 08, 2019	Sep	NEWA
>A>	AB		150MG	A206912	005	Oct 08, 2019	Sep	NEWA
>A>	AB		200MG	A206912	006	Oct 08, 2019	Sep	NEWA
>A>	AB		225MG	A206912	007	Oct 08, 2019	Sep	NEWA
>A>	AB		300MG	A206912	008	Oct 08, 2019	Sep	NEWA
>A>	AB	MYLAN	25MG	A091228	001	Sep 20, 2019	Sep	NEWA
>A>	AB		50MG	A091228	002	Sep 20, 2019	Sep	NEWA
>A>	AB		75MG	A091228	003	Sep 20, 2019	Sep	NEWA
>A>	AB		100MG	A091228	004	Sep 20, 2019	Sep	NEWA
>A>	AB		150MG	A091228	005	Sep 20, 2019	Sep	NEWA
>A>	AB		200MG	A091228	006	Sep 20, 2019	Sep	NEWA
>A>	AB		225MG	A091228	007	Sep 20, 2019	Sep	NEWA
>A>	AB		300MG	A091228	008	Sep 20, 2019	Sep	NEWA

PROBENECID
TABLET;ORAL
PROBENECID

>D>	AB	! MYLAN	500MG	A084211	002	Jan 13, 1976	Sep	CHRS
>A>	AB		500MG	A084211	002	Jan 13, 1976	Sep	CHRS
>D>	AB	WATSON LABS TEVA	500MG	A084442	004	Mar 29, 1983	Sep	CHRS
>A>		!	500MG	A084442	004	Mar 29, 1983	Sep	CHRS

PROPRANOLOL HYDROCHLORIDE
CAPSULE, EXTENDED RELEASE;ORAL
PROPRANOLOL HYDROCHLORIDE

>A>	AB	ADARE PHARMS INC	60MG	A078703	001	Jul 15, 2011	Sep	CAHN
>A>	AB		80MG	A078703	002	Jul 15, 2011	Sep	CAHN
>A>	AB		120MG	A078703	003	Jul 15, 2011	Sep	CAHN
>A>	AB		160MG	A078703	004	Jul 15, 2011	Sep	CAHN
>D>	AB	RP SCHERER	60MG	A078703	001	Jul 15, 2011	Sep	CAHN
>D>	AB		80MG	A078703	002	Jul 15, 2011	Sep	CAHN
>D>	AB		120MG	A078703	003	Jul 15, 2011	Sep	CAHN
>D>	AB		160MG	A078703	004	Jul 15, 2011	Sep	CAHN

TABLET;ORAL
PROPRANOLOL HYDROCHLORIDE

>A>	@ ANI PHARMS INC	60MG	A071791	001	Jul 15, 1987	Sep	CAHN
>D>	@ WATSON LABS	60MG	A071791	001	Jul 15, 1987	Sep	CAHN

PYRIDOSTIGMINE BROMIDE
TABLET;ORAL
PYRIDOSTIGMINE BROMIDE

>D>		APNAR PHARMA LP	30MG	A211181	002	May 14, 2019	Sep	CAHN
>D>	AB		60MG	A211181	001	Jul 20, 2018	Sep	CAHN
>A>		ELYSIUM	30MG	A211181	002	May 14, 2019	Sep	CAHN
>A>	AB		60MG	A211181	001	Jul 20, 2018	Sep	CAHN

ADDITIONS/DELETIONS FOR PRESCRIPTION DRUG PRODUCT LIST

		QUINIDINE GLUCONATE							
		TABLET, EXTENDED RELEASE;ORAL							
		QUINAGLUTE							
>D>		@ BAYER HLTHCARE	324MG	N016647	001	Dec 08, 1969	Sep	CRLD	
>A>		+ @	324MG	N016647	001	Dec 08, 1969	Sep	CRLD	
		QUINIDINE GLUCONATE							
>D>	BX	! SUN PHARM INDUSTRIES	324MG	A089338	001	Feb 11, 1987	Sep	CTEC	
>A>		!	324MG	A089338	001	Feb 11, 1987	Sep	CTEC	
		RASAGILINE							
		TABLET;ORAL							
		RASAGILINE							
>A>	AB	INDOCO REMEDIES	EQ 0.5MG BASE	A206153	001	Oct 04, 2019	Sep	NEWA	
>A>	AB		EQ 1MG BASE	A206153	002	Oct 04, 2019	Sep	NEWA	
		RISPERIDONE							
		TABLET;ORAL							
		RISPERIDONE							
>D>	AB	CEYONE	0.25MG	A078269	001	Oct 08, 2008	Sep	CAHN	
>D>	AB		0.5MG	A078269	002	Oct 08, 2008	Sep	CAHN	
>D>	AB		1MG	A078269	003	Oct 08, 2008	Sep	CAHN	
>D>	AB		2MG	A078269	004	Oct 08, 2008	Sep	CAHN	
>D>	AB		3MG	A078269	005	Oct 08, 2008	Sep	CAHN	
>D>	AB		4MG	A078269	006	Oct 08, 2008	Sep	CAHN	
>A>	AB	RISING	0.25MG	A078269	001	Oct 08, 2008	Sep	CAHN	
>A>	AB		0.5MG	A078269	002	Oct 08, 2008	Sep	CAHN	
>A>	AB		1MG	A078269	003	Oct 08, 2008	Sep	CAHN	
>A>	AB		2MG	A078269	004	Oct 08, 2008	Sep	CAHN	
>A>	AB		3MG	A078269	005	Oct 08, 2008	Sep	CAHN	
>A>	AB		4MG	A078269	006	Oct 08, 2008	Sep	CAHN	
		ROPINIROLE HYDROCHLORIDE							
		TABLET;ORAL							
		ROPINIROLE HYDROCHLORIDE							
>D>	AB	LAX	EQ 0.25MG BASE	A079165	001	Feb 07, 2012	Sep	CAHN	
>D>	AB		EQ 0.5MG BASE	A079165	002	Feb 07, 2012	Sep	CAHN	
>D>	AB		EQ 1MG BASE	A079165	003	Feb 07, 2012	Sep	CAHN	
>D>	AB		EQ 2MG BASE	A079165	004	Feb 07, 2012	Sep	CAHN	
>D>	AB		EQ 3MG BASE	A079165	005	Feb 07, 2012	Sep	CAHN	
>D>	AB		EQ 4MG BASE	A079165	006	Feb 07, 2012	Sep	CAHN	
>D>	AB		EQ 5MG BASE	A079165	007	Feb 07, 2012	Sep	CAHN	
>A>	AB	MLV	EQ 0.25MG BASE	A079165	001	Feb 07, 2012	Sep	CAHN	
>A>	AB		EQ 0.5MG BASE	A079165	002	Feb 07, 2012	Sep	CAHN	
>A>	AB		EQ 1MG BASE	A079165	003	Feb 07, 2012	Sep	CAHN	
>A>	AB		EQ 2MG BASE	A079165	004	Feb 07, 2012	Sep	CAHN	
>A>	AB		EQ 3MG BASE	A079165	005	Feb 07, 2012	Sep	CAHN	
>A>	AB		EQ 4MG BASE	A079165	006	Feb 07, 2012	Sep	CAHN	
>A>	AB		EQ 5MG BASE	A079165	007	Feb 07, 2012	Sep	CAHN	
		ROSIGLITAZONE MALEATE							
		TABLET;ORAL							
		ROSIGLITAZONE MALEATE							
>A>		@ ANI PHARMS INC	EQ 2MG BASE	A076747	001	Jan 25, 2013	Sep	CAHN	
>A>		@	EQ 4MG BASE	A076747	002	Jan 25, 2013	Sep	CAHN	
>A>		@	EQ 8MG BASE	A076747	003	Jan 25, 2013	Sep	CAHN	
>D>		@ TEVA	EQ 2MG BASE	A076747	001	Jan 25, 2013	Sep	CAHN	
>D>		@	EQ 4MG BASE	A076747	002	Jan 25, 2013	Sep	CAHN	
>D>		@	EQ 8MG BASE	A076747	003	Jan 25, 2013	Sep	CAHN	
		SAPROPTERIN DIHYDROCHLORIDE							
		POWDER;ORAL							
		KUVAN							
>D>	AB	+ BIOMARIN PHARM	500MG/PACKET	N205065	002	Oct 27, 2015	Sep	CTEC	
>A>		+	500MG/PACKET	N205065	002	Oct 27, 2015	Sep	CTEC	
		SAPROPTERIN DIHYDROCHLORIDE							
>D>	AB	PAR PHARM INC	500MG/PACKET	A210027	001	Aug 20, 2019	Sep	DISC	
>A>		@	500MG/PACKET	A210027	001	Aug 20, 2019	Sep	DISC	

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		SEMAGLUTIDE						
>A>		TABLET;ORAL						
>A>		RYBELSUS						
>A>	+	NOVO	3MG	N213051	001	Sep 20, 2019	Sep	NEWA
>A>	+		7MG	N213051	002	Sep 20, 2019	Sep	NEWA
>A>	+!		14MG	N213051	003	Sep 20, 2019	Sep	NEWA
		SODIUM CHLORIDE						
		INJECTABLE;INJECTION						
		SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER						
>A>	AP	JUBILANT CADISTA	9MG/ML	A203352	001	May 18, 2016	Sep	CAHN
>D>	AP	JUBILANT HOLLISTRSTR	9MG/ML	A203352	001	May 18, 2016	Sep	CAHN
		SODIUM NITROPRUSSIDE						
		INJECTABLE;INJECTION						
		SODIUM NITROPRUSSIDE						
>D>	AP	NAMIGEN LLC	25MG/ML	A207426	001	Dec 08, 2016	Sep	CAHN
>A>	AP	SAGENT PHARMS INC	25MG/ML	A207426	001	Dec 08, 2016	Sep	CAHN
		SODIUM POLYSTYRENE SULFONATE						
		POWDER;ORAL, RECTAL						
		SODIUM POLYSTYRENE SULFONATE						
>D>	AA	AILEX PHARMS LLC	454GM/BOT	A206815	001	Feb 18, 2016	Sep	CAHN
>A>	AA	NOVELGENIX THERAPS	454GM/BOT	A206815	001	Feb 18, 2016	Sep	CAHN
		SOLIFENACIN SUCCINATE						
		TABLET;ORAL						
		SOLIFENACIN SUCCINATE						
>A>	AB	STRIDES PHARMA	5MG	A212214	001	Sep 26, 2019	Sep	NEWA
>A>	AB		10MG	A212214	002	Sep 26, 2019	Sep	NEWA
		SUCCINYLCHOLINE CHLORIDE						
		INJECTABLE;INJECTION						
		SUCCINYLCHOLINE CHLORIDE						
>A>	AP	GPP	20MG/ML	A212638	001	Oct 09, 2019	Sep	NEWA
		SULFAMETHOXAZOLE; TRIMETHOPRIM						
		INJECTABLE;INJECTION						
		SULFAMETHOXAZOLE AND TRIMETHOPRIM						
>A>	AP	ANDA REPOSITORY	80MG/ML;16MG/ML	A212231	001	Jun 26, 2019	Sep	CAHN
>D>	AP	SOMERSET THERAPS LLC	80MG/ML;16MG/ML	A212231	001	Jun 26, 2019	Sep	CAHN
		SUMATRIPTAN						
		SPRAY;NASAL						
		TOSYMRA						
>D>	+!	UPSHER SMITH LABS	10MG/SPRAY	N210884	001	Jan 25, 2019	Sep	CAHN
>A>	+!		10MG/SPRAY	N210884	001	Jan 25, 2019	Sep	CAHN
		SUMATRIPTAN SUCCINATE						
		INJECTABLE;SUBCUTANEOUS						
		SUMATRIPTAN SUCCINATE						
>D>	AP	MYLAN LABS LTD	EQ 6MG BASE/0.5ML (EQ 12MG BASE/ML)	A203322	001	Apr 14, 2014	Sep	DISC
>A>		@	EQ 6MG BASE/0.5ML (EQ 12MG BASE/ML)	A203322	001	Apr 14, 2014	Sep	DISC
		POWDER;INHALATION						
		ONZETRA XSAIL						
>D>	+!	AVANIR PHARMS	EQ 11MG BASE	N206099	001	Jan 27, 2016	Sep	CDFR
>A>		POWDER;NASAL						
>A>		ONZETRA XSAIL						
>A>	+!	AVANIR PHARMS	EQ 11MG BASE	N206099	001	Jan 27, 2016	Sep	CDFR
>A>	+!	CURRAX	EQ 11MG BASE	N206099	001	Jan 27, 2016	Sep	CAHN
		TADALAFIL						
		TABLET;ORAL						
		TADALAFIL						
>A>	AB	MACLEODS PHARMS LTD	2.5MG	A207244	001	Oct 07, 2019	Sep	NEWA
>A>	AB		5MG	A207244	002	Oct 07, 2019	Sep	NEWA
>A>	AB		10MG	A207244	003	Oct 07, 2019	Sep	NEWA
>A>	AB1		20MG	A207244	004	Oct 07, 2019	Sep	NEWA
>A>	AB2		20MG	A207290	001	Oct 16, 2019	Sep	NEWA
>D>	AB	WATSON LABS INC	2.5MG	A205885	001	Mar 29, 2019	Sep	DISC

		TADALAFIL						
		TABLET;ORAL						
		TADALAFIL						
>A>		@	2.5MG	A205885	001	Mar 29, 2019	Sep	DISC
>D>	AB		5MG	A205885	002	Mar 29, 2019	Sep	DISC
>A>		@	5MG	A205885	002	Mar 29, 2019	Sep	DISC
>D>	AB		10MG	A205885	003	Mar 29, 2019	Sep	DISC
>A>		@	10MG	A205885	003	Mar 29, 2019	Sep	DISC
>D>	AB1		20MG	A205885	004	Mar 29, 2019	Sep	DISC
>A>		@	20MG	A205885	004	Mar 29, 2019	Sep	DISC
		TECHNETIUM TC-99M PENTETATE KIT						
		INJECTABLE;INJECTION						
>A>		DRAXIMAGE DTPA						
>A>		+! JUBILANT DRAXIMAGE	N/A	N018511	001	Dec 29, 1989	Sep	CTNA
>D>		DTPA						
>D>		+! JUBILANT DRAXIMAGE	N/A	N018511	001	Dec 29, 1989	Sep	CTNA
		TEGASEROD MALEATE						
		TABLET;ORAL						
		ZELNORM						
>D>		+ @ ALFASIGMA	EQ 6MG BASE	N021200	002	Jul 24, 2002	Sep	CMFD
>A>		+!	EQ 6MG BASE	N021200	002	Jul 24, 2002	Sep	CMFD
>A>		TENAPANOR HYDROCHLORIDE						
>A>		TABLET;ORAL						
>A>		IBSRELA						
>A>		+! ARDELYX INC	EQ 50MG BASE	N211801	001	Sep 12, 2019	Sep	NEWA
		TESTOSTERONE						
		GEL, METERED;TRANSDERMAL						
		TESTOSTERONE						
>A>	AB	TWI PHARMS	1.62% (20.25MG/1.25GM ACTUATION)	A209390	001	Sep 23, 2019	Sep	NEWA
		THIOTHIXENE HYDROCHLORIDE						
		CONCENTRATE;ORAL						
		THIOTHIXENE HYDROCHLORIDE INTENSOL						
>D>		@ CYCLE PHARMS LTD	EQ 5MG BASE/ML	A073494	001	Jun 30, 1992	Sep	CAHN
>A>		@ HIKMA	EQ 5MG BASE/ML	A073494	001	Jun 30, 1992	Sep	CAHN
		TIMOLOL MALEATE						
		TABLET;ORAL						
		TIMOLOL MALEATE						
>A>		@ ANI PHARMS INC	5MG	A072917	001	Jul 31, 1991	Sep	CAHN
>A>		@	10MG	A072918	001	Jul 31, 1991	Sep	CAHN
>A>		@	20MG	A072919	001	Jul 31, 1991	Sep	CAHN
>A>	AB	ELYSIUM	5MG	A207556	001	May 02, 2019	Sep	CAHN
>A>	AB		10MG	A207556	002	May 02, 2019	Sep	CAHN
>A>	AB		20MG	A207556	003	May 02, 2019	Sep	CAHN
>D>	AB	INVATECH PHARMA	5MG	A207556	001	May 02, 2019	Sep	CAHN
>D>	AB		10MG	A207556	002	May 02, 2019	Sep	CAHN
>D>	AB		20MG	A207556	003	May 02, 2019	Sep	CAHN
>D>		@ WATSON LABS	5MG	A072917	001	Jul 31, 1991	Sep	CAHN
>D>		@	10MG	A072918	001	Jul 31, 1991	Sep	CAHN
>D>		@	20MG	A072919	001	Jul 31, 1991	Sep	CAHN
		TIZANIDINE HYDROCHLORIDE						
		CAPSULE;ORAL						
		TIZANIDINE HYDROCHLORIDE						
>A>	AB	NOVAST LABS	EQ 2MG BASE	A210267	001	Mar 12, 2019	Sep	CAHN
>A>	AB		EQ 4MG BASE	A210267	002	Mar 12, 2019	Sep	CAHN
>A>	AB		EQ 6MG BASE	A210267	003	Mar 12, 2019	Sep	CAHN
>D>	AB	RICONPHARMA LLC	EQ 2MG BASE	A210267	001	Mar 12, 2019	Sep	CAHN
>D>	AB		EQ 4MG BASE	A210267	002	Mar 12, 2019	Sep	CAHN
>D>	AB		EQ 6MG BASE	A210267	003	Mar 12, 2019	Sep	CAHN
		TABLET;ORAL						
		TIZANIDINE HYDROCHLORIDE						
>A>	AB	ANI PHARMS INC	EQ 2MG BASE	A076284	001	Jul 03, 2002	Sep	CAHN
>A>	AB		EQ 4MG BASE	A076284	002	Jul 03, 2002	Sep	CAHN
>D>	AB	TEVA	EQ 2MG BASE	A076284	001	Jul 03, 2002	Sep	CAHN

TIZANIDINE HYDROCHLORIDE
TABLET;ORAL
TIZANIDINE HYDROCHLORIDE

>D>	AB		EQ 4MG BASE	A076284	002	Jul 03, 2002	Sep	CAHN

TOLCAPONE
TABLET;ORAL
TOLCAPONE

>D>	AB	INGENUS PHARMS LLC	100MG	A208937	001	Aug 07, 2018	Sep	CAHN
>D>	AB	KINEDEXE UK	100MG	A210095	001	Aug 01, 2019	Sep	CAHN
>A>	AB	MAYNE PHARMA	100MG	A210095	001	Aug 01, 2019	Sep	CAHN
>A>	AB	NOVAST LABS	100MG	A208937	001	Aug 07, 2018	Sep	CAHN

TOLMETIN SODIUM
CAPSULE;ORAL
TOLMETIN SODIUM

>A>		@ ANI PHARMS INC	EQ 400MG BASE	A073519	001	May 29, 1992	Sep	CAHN
>D>		@ TEVA	EQ 400MG BASE	A073519	001	May 29, 1992	Sep	CAHN

TRAMADOL HYDROCHLORIDE
TABLET, EXTENDED RELEASE;ORAL
TRAMADOL HYDROCHLORIDE

>D>	AB1	AUROBINDO PHARMA LTD	100MG	A204421	001	Oct 20, 2015	Sep	DISC
>A>		@	100MG	A204421	001	Oct 20, 2015	Sep	DISC
>D>	AB1		200MG	A204421	002	Oct 20, 2015	Sep	DISC
>A>		@	200MG	A204421	002	Oct 20, 2015	Sep	DISC
>D>	AB1		300MG	A204421	003	Oct 20, 2015	Sep	DISC
>A>		@	300MG	A204421	003	Oct 20, 2015	Sep	DISC

TREPROSTINIL
INJECTABLE;IV (INFUSION), SUBCUTANEOUS
TREPROSTINIL

>A>	AP	PAR STERILE PRODUCTS	1MG/ML	A209382	001	Sep 24, 2019	Sep	NEWA
>A>	AP		2.5MG/ML	A209382	002	Sep 24, 2019	Sep	NEWA
>A>	AP		5MG/ML	A209382	003	Sep 24, 2019	Sep	NEWA
>A>	AP		10MG/ML	A209382	004	Sep 24, 2019	Sep	NEWA
>A>	AP	TEVA PHARMS USA	1MG/ML	A206648	001	Sep 26, 2019	Sep	NEWA
>A>	AP		2.5MG/ML	A206648	002	Sep 26, 2019	Sep	NEWA
>A>	AP		5MG/ML	A206648	003	Sep 26, 2019	Sep	NEWA
>A>	AP		10MG/ML	A206648	004	Sep 26, 2019	Sep	NEWA

TRIAMCINOLONE ACETONIDE
CREAM;TOPICAL
TRIAMCINOLONE ACETONIDE

>A>	AT	MLV	0.025%	A040671	001	Jun 09, 2006	Sep	CAHN
>A>	AT		0.1%	A040671	002	Jun 09, 2006	Sep	CAHN
>D>	AT	SAPTALIS PHARMS	0.025%	A040671	001	Jun 09, 2006	Sep	CAHN
>D>	AT		0.1%	A040671	002	Jun 09, 2006	Sep	CAHN

LOTION;TOPICAL
TRIAMCINOLONE ACETONIDE

>A>	AT	ALLIED	0.1%	A040672	002	Dec 13, 2006	Sep	CAHN
>D>	AT	SAPTALIS PHARMS	0.1%	A040672	002	Dec 13, 2006	Sep	CAHN

TRIENTINE HYDROCHLORIDE
CAPSULE;ORAL
SYPRINE

>D>	AB	+! ATON	250MG	N019194	001	Nov 08, 1985	Sep	CAHN
>A>	AB	+! BAUSCH	250MG	N019194	001	Nov 08, 1985	Sep	CAHN

TRIENTINE HYDROCHLORIDE

>A>	AB	KADMON PHARMS LLC	250MG	A209415	001	Sep 16, 2019	Sep	NEWA
>A>	AB	PAR PHARM INC	250MG	A210096	001	Sep 25, 2019	Sep	NEWA

VERAPAMIL HYDROCHLORIDE
SOLUTION;INTRAVENOUS
VERAPAMIL HYDROCHLORIDE

>A>	AP	ANDA REPOSITORY	5MG/2ML (2.5MG/ML)	A211035	001	Jun 18, 2018	Sep	CAHN
>A>	AP		10MG/4ML (2.5MG/ML)	A211035	002	Jun 18, 2018	Sep	CAHN
>D>	AP	SOMERSET THERAPS LLC	5MG/2ML (2.5MG/ML)	A211035	001	Jun 18, 2018	Sep	CAHN
>D>	AP		10MG/4ML (2.5MG/ML)	A211035	002	Jun 18, 2018	Sep	CAHN

VILAZODONE HYDROCHLORIDE
TABLET;ORAL
VIIBRYD

>D>		+!	ALLERGAN SALES LLC	10MG	N022567	001	Jan 21, 2011	Sep	CFTG
>A>	AB	+!		10MG	N022567	001	Jan 21, 2011	Sep	CFTG
>D>		+		20MG	N022567	002	Jan 21, 2011	Sep	CFTG
>A>	AB	+		20MG	N022567	002	Jan 21, 2011	Sep	CFTG
>D>		+		40MG	N022567	003	Jan 21, 2011	Sep	CFTG
>A>	AB	+		40MG	N022567	003	Jan 21, 2011	Sep	CFTG

>A> VILAZODONE HYDROCHLORIDE

>A>	AB		TEVA PHARMS USA	10MG	A208212	001	Sep 30, 2019	Sep	NFTG
>A>	AB			20MG	A208212	002	Sep 30, 2019	Sep	NFTG
>A>	AB			40MG	A208212	003	Sep 30, 2019	Sep	NFTG

VINORELBINE TARTRATE
INJECTABLE;INJECTION
VINORELBINE TARTRATE

>D>	AP		INGENUS PHARMS LLC	EQ 10MG BASE/ML	A208997	001	Aug 05, 2019	Sep	CAHN
>A>	AP		NOVAST LABS	EQ 10MG BASE/ML	A208997	001	Aug 05, 2019	Sep	CAHN

VORICONAZOLE
INJECTABLE;INTRAVENOUS
VORICONAZOLE

>A>	AP		ALVOGEN	200MG/VIAL	A206398	001	Mar 23, 2016	Sep	CAHN
>D>	AP		ALVOGEN INC	200MG/VIAL	A206398	001	Mar 23, 2016	Sep	CAHN

ZOLMITRIPTAN
TABLET, ORALLY DISINTEGRATING;ORAL
ZOLMITRIPTAN

>A>	AB		MYLAN	2.5MG	A202855	001	Sep 20, 2019	Sep	NEWA
>A>	AB			5MG	A202855	002	Sep 20, 2019	Sep	NEWA

ADDITIONS/DELETIONS FOR OTC DRUG PRODUCT LIST

	ACETAMINOPHEN							
	TABLET, EXTENDED RELEASE;ORAL							
	ACETAMINOPHEN							
>D>	@ HERITAGE PHARMA	650MG	A207035	001	May 31, 2018	Sep	CMFD	
>A>		650MG	A207035	001	May 31, 2018	Sep	CMFD	
	CETIRIZINE HYDROCHLORIDE							
	SYRUP;ORAL							
	CHILDREN'S CETIRIZINE HYDROCHLORIDE ALLERGY							
>D>	APNAR PHARMA LP	5MG/5ML	A091327	001	Oct 17, 2011	Sep	CAHN	
>A>	ATHEM	5MG/5ML	A091327	001	Oct 17, 2011	Sep	CAHN	
	CHILDREN'S CETIRIZINE HYDROCHLORIDE HIVES RELIEF							
>D>	APNAR PHARMA LP	5MG/5ML	A091327	002	Oct 17, 2011	Sep	CAHN	
>A>	ATHEM	5MG/5ML	A091327	002	Oct 17, 2011	Sep	CAHN	
	ESOMEPRAZOLE MAGNESIUM							
	CAPSULE, DELAYED RELEASE;ORAL							
	ESOMEPRAZOLE MAGNESIUM							
>A>	MYLAN	EQ 20MG BASE	A212376	001	Oct 16, 2019	Sep	NEWA	
	IBUPROFEN							
	SUSPENSION;ORAL							
>D>	CHILDREN'S ELIXSURE							
>D>	MOBERG PHARMA NORTH	100MG/5ML	N021604	001	Jan 07, 2004	Sep	DISC	
>A>	@	100MG/5ML	N021604	001	Jan 07, 2004	Sep	DISC	
	ISOPROPYL ALCOHOL							
	SOLUTION;TOPICAL							
>D>	ZURAGARD							
>D>	+! ZUREX PHARMA	70% (10.5ML)	N210872	001	Apr 26, 2019	Sep	DISC	
>A>	+ @	70% (10.5ML)	N210872	001	Apr 26, 2019	Sep	DISC	
	LEVONORGESTREL							
	TABLET;ORAL							
	LEVONORGESTREL							
>A>	NAARI PTE LTD	1.5MG	A202380	001	May 29, 2015	Sep	CAHN	
>D>	OC PHARMA	1.5MG	A202380	001	May 29, 2015	Sep	CAHN	
	NAPROXEN SODIUM							
	TABLET;ORAL							
	ALEVE							
>D>	+! BAYER	EQ 200MG BASE	N020204	002	Jan 11, 1994	Sep	CPOT	
>A>	+!	220MG	N020204	002	Jan 11, 1994	Sep	CPOT	
	NAPROXEN SODIUM							
>D>	AMNEAL PHARMS NY	EQ 200MG BASE	A079096	001	Dec 16, 2008	Sep	CPOT	
>A>		220MG	A079096	001	Dec 16, 2008	Sep	CPOT	
>D>	AUROBINDO PHARMA LTD	EQ 200MG BASE	A205497	001	Mar 18, 2016	Sep	CPOT	
>A>		220MG	A205497	001	Mar 18, 2016	Sep	CPOT	
>D>	CONTRACT PHARMACAL	EQ 200MG BASE	A074635	001	Jan 13, 1997	Sep	CPOT	
>D>	@	EQ 200MG BASE	A074789	001	Feb 27, 1997	Sep	CPOT	
>A>		220MG	A074635	001	Jan 13, 1997	Sep	CPOT	
>A>	@	220MG	A074789	001	Feb 27, 1997	Sep	CPOT	
>D>	DR REDDYS LABS INC	EQ 200MG BASE	A075168	001	Jul 28, 1998	Sep	CPOT	
>A>		220MG	A075168	001	Jul 28, 1998	Sep	CPOT	
>D>	GRANULES INDIA	EQ 200MG BASE	A091353	001	Sep 20, 2011	Sep	CPOT	
>A>		220MG	A091353	001	Sep 20, 2011	Sep	CPOT	
>D>	LNK INTL INC	EQ 200MG BASE	A204872	001	Jan 23, 2017	Sep	CPOT	
>A>		220MG	A204872	001	Jan 23, 2017	Sep	CPOT	
>D>	MARKSANS PHARMA	EQ 200MG BASE	A090545	001	Mar 16, 2011	Sep	CPOT	
>A>		220MG	A090545	001	Mar 16, 2011	Sep	CPOT	
>D>	NOVELGENIX THERAPS	EQ 200MG BASE	A207612	001	Nov 16, 2018	Sep	CPOT	
>A>		220MG	A207612	001	Nov 16, 2018	Sep	CPOT	
>D>	PERRIGO	EQ 200MG BASE	A074661	001	Jan 13, 1997	Sep	CPOT	
>A>		220MG	A074661	001	Jan 13, 1997	Sep	CPOT	

NAPROXEN SODIUM
TABLET;ORAL
NAPROXEN SODIUM

>D>	@ PLD ACQUISITIONS LLC	EQ 200MG BASE	A074646	001	Jan 13, 1997	Sep	CPOT
>A>	@	220MG	A074646	001	Jan 13, 1997	Sep	CPOT
>D>	SUN PHARM INDS LTD	EQ 200MG BASE	A091183	001	May 20, 2011	Sep	CPOT
>A>		220MG	A091183	001	May 20, 2011	Sep	CPOT
>D>	YICHANG HUMANWELL	EQ 200MG BASE	A212033	001	Aug 30, 2019	Sep	CPOT
>A>		220MG	A212033	001	Aug 30, 2019	Sep	CPOT

NAPROXEN SODIUM; PSEUDOEPHEDRINE HYDROCHLORIDE
TABLET, EXTENDED RELEASE;ORAL
ALEVE-D SINUS & COLD

>D>	+! BAYER	EQ 200MG BASE;120MG	N021076	001	Nov 29, 1999	Sep	CPOT
>A>	+!	220MG;120MG	N021076	001	Nov 29, 1999	Sep	CPOT

NAPROXEN SODIUM AND PSEUDOEPHEDRINE HYDROCHLORIDE

>D>	DR REDDYS LABS INC	EQ 220MG BASE;120MG	A077381	001	Sep 27, 2006	Sep	CPOT
>A>		220MG;120MG	A077381	001	Sep 27, 2006	Sep	CPOT
>D>	PERRIGO	EQ 200MG BASE;120MG	A076518	001	Mar 17, 2004	Sep	CPOT
>A>		220MG;120MG	A076518	001	Mar 17, 2004	Sep	CPOT

POLYETHYLENE GLYCOL 3350
FOR SOLUTION;ORAL
POLYETHYLENE GLYCOL 3350

>D>	APNAR PHARMA LP	17GM/SCOOPFUL	A202071	001	Dec 28, 2012	Sep	CAHN
>A>	NOVELGENIX THERAPS	17GM/SCOOPFUL	A202071	001	Dec 28, 2012	Sep	CAHN

CURRENT MONTH ADDS/DELETES LIST NOTE:

The List is sorted by Ingredient(s) and, within each grouping, by the Dosage Form; Route and then by trade name.

The individual product record contains the Therapeutic Equivalence Code, Reference Listed Drug symbol, Reference Standard Drug symbol, applicant holder, strength(s), New Drug Application number, product number, and approval date. The last two columns describe the action. The Action Month is the CS month the action occurred. The OB Action is the type of change that has occurred.

New ingredient(s), new dosage form; route(s), new trade names, and new product additions are preceded by >A> during the action month. The change month is the current CS month; the change code for new approvals is NEWA.

Changes to currently listed products will list two records. The deleted product record will be proceeded by >D>. The product record change addition being made will be preceded by >A>.

The change code description:

NEWA	New drug product approval usually in the supplement month.
NFTG	New first time generic approval.
CAHN**	Applicant holder firm name has changed.
CAIN	Change. There has been a change in the Ingredient(s) name. All products will be deleted under the old name and all products will be added under the changed ingredient(s) name.
CDFR	Change. Dosage Form; Route of Administration.
CFTG	Change. A first time generic for the innovator product. A TE Code is added.
CMFD	Change. The product is moved from the Discontinued Section due to a change in marketing status.
CMS1	Change. Miscellaneous addition to list.
CMS2	Change. Miscellaneous deletion from list.
CPOT	Change. Potency amount/unit.
CRLD	Change. Reference Listed Drug.
CHRS	Change. Reference Standard.
CTEC	Change. Therapeutic Equivalence Code.
CTNA	Change. Trade Name.
DISC	Discontinued. The Rx or OTC listed product is not being marketed and will be moved to the discontinued section in the next edition.

**Note:
The Cumulative Supplement (CS) currently displays a condensed 20 character collapsed applicant holder firm name and the Electronic Orange Book(EOB)query may display up to a 240 character full applicant holder firm name. An applicant holder firm name change usually changes both the collapsed name and long name. On occasion, only the long name is changed resulting in the CS displaying only the collapsed name for the >D> and >A> action. The new firm long name will display in the EOB query.

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https://web.archive.org/web/20061009113956/http://www.ismp-canada.org/download/ISMPCSB2006-02PotassiumPhosphates.pdf

The Institute for Safe Medication Practices Canada (ISMP Canada) is an independent national nonprofit agency established for the collection and analysis of medication error reports and the development of recommendations for the enhancement of patient safety.

The Healthcare Insurance Reciprocal of Canada (HIROC) is a member-owned expert provider of professional and general liability coverage and risk management support.

Volume 6, Issue 2

ISMP Canada Safety Bulletin

April 25, 2006

Safety Strategies for Potassium Phosphates Injection

The dangers associated with inadvertent administration of concentrated **potassium** solutions are well known. ISMP Canada and the Canadian Council on Health Services Accreditation (CCHSA) recommend that concentrated electrolytes be removed from patient care areas.† Many hospitals have succeeded in removing concentrated potassium *chloride* products from patient care areas. The approach to removal of concentrated potassium *phosphates* solutions, however, is not as straightforward, largely due to the lack of availability of commercially prepared premixed infusion solutions.

Safety Issues with Potassium Phosphates Injection

Potassium phosphates injection is designated as a "high-alert" medication for the following reasons:

- **Vials of potassium phosphates contain more than twice the concentration of potassium (4.4 mmol/mL) compared to potassium chloride concentrate (2 mmol/mL). If inadequately diluted or administered too rapidly, intravenous potassium phosphate can cause serious adverse consequences.**
- Product labels for commercially available potassium phosphates injection can be confusing because of the nature of the product (see Figure 1 for one example). A variety of measurement units (mg, mEq, mmol, mOsm, mL) are used on the labels. The variety of information may cause confusion and may lead to calculation errors during preparation of doses for intravenous infusion.

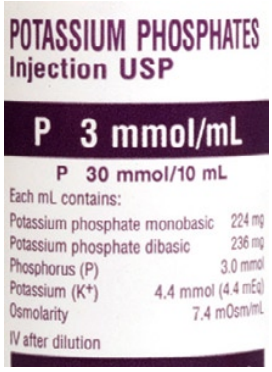


Figure 1: Photograph of a commercially available potassium phosphates injection label illustrating the potential for confusion because of the nature of the product.

- Variations in the way prescribers express doses of potassium phosphate may lead to error-prone conversions between milligrams (mg), milliequivalents (mEq), and millimoles (mmol) for the phosphorus component, as well as inattention to the amount of potassium delivered with each dose.

Note: The terms phosphate and phosphorus are often used interchangeably and this is acceptable for the purposes of prescribing. Although phosphorus is the elemental form and phosphate exists in various ionic forms, the millimolar content of phosphorous can be considered virtually identical with that of phosphate. Therefore when prescribing a phosphate product, the recommendation (see below) is to specify the dose in millimoles (mmol).

Background Information on the Treatment of Hypophosphatemia

Hypophosphatemia is a frequently encountered metabolic complication in critically ill hospital inpatients. Moderate hypophosphatemia is usually defined as serum phosphate in the range of 0.4-0.8 mmol/L and severe hypophosphatemia as a level below 0.4 mmol/L.[1,2] Oral phosphate supplementation is preferred for asymptomatic patients with mild to moderate hypophosphatemia when the enteral route is feasible. Intravenous phosphate supplementation is necessary for patients with severe hypophosphatemia, symptomatic patients with moderate hypophosphatemia, or patients for whom the enteral route is not feasible. Either potassium phosphates or sodium phosphates may be used for parenteral phosphate replacement. The electrolyte content of each of these products is noted in Figure 2 below.

Potassium Phosphates Injection
10 mL vial
Each millilitre supplies:
4.4 mmol of potassium
3 mmol of phosphorus

Sodium Phosphates Injection
10 mL vial
Each millilitre supplies:
4 mmol of sodium
3 mmol of phosphorus

Figure 2: Electrolyte content for potassium phosphates and sodium phosphates injections, respectively. Either product may be used for parenteral phosphate replacement.

Recommendations for Preventing Adverse Events:

1. Develop Standard Protocols for Intravenous Phosphate Supplementation

   As an essential first step to improving safety, it is recommended that institutions develop standardized dosing and monitoring protocols for intravenous phosphate replacement therapy. The development of such protocols will encourage the use of standardized doses and solutions. There is confusion about the appropriate dosing and administration of phosphate infusions, regardless of whether potassium phosphate or

† A comprehensive package to assist in the removal of concentrated potassium chloride is available through ISMP Canada.

sodium phosphate is used. This confusion may arise because the product monograph lacks clear dosing recommendations, because the labelling on the vials is confusing, and because clinical studies have used a variety of dosing regimens.

2. Develop 'Order Sets' (Preprinted or Electronic) for Phosphate Infusions

   To ensure compliance with standard protocols, the development of order sets (preprinted or electronic) for phosphate infusions should be considered. These orders should clearly specify the **dose in mmol** of phosphate, the type and volume of infusion solution, and the recommended rate of administration. As well, the mmol of potassium or sodium provided per dose should also be stated on the preprinted orders. The text for labels for infusion bags and entries for computer-generated medication administration records (MARs) should also follow a standard format.

3. Remove Potassium Phosphates Injection from Patient Care Areas

   The removal of concentrated potassium phosphates injection from patient care areas is an important patient safety initiative. The approach will depend on the decisions that are made during the development of standard protocols for phosphate infusion.

   - Preferential use of sodium phosphate infusions for parenteral phosphate replacement may be an option for minimizing risk, especially when infusion bags cannot be prepared in the pharmacy. Sodium phosphates injection provides the same phosphate content as potassium phosphates injection, and presents less risk to patients if improperly diluted or rapidly infused. In a recent publication by Esmail et al[3] recommendations include the substitution of sodium phosphate for potassium phosphate for certain patients to facilitate removal of concentrated potassium phosphate from patient care areas. Since the product labels for sodium phosphates injection may be as confusing as those for potassium phosphates injection, it is crucial to establish standard dosing protocols and guidelines for the preparation, labelling and administration of infusion bags.
   - If it is decided that potassium phosphate infusion is desirable for some or all patients with hypophosphatemia, the removal of the concentrated product from patient care areas will require a system which includes pharmacy-based preparation of standard infusion bags of potassium phosphate.

Collaboration among prescribers, nurses, and pharmacy personnel will be key to each institution's success in implementing safety strategies for removing potassium phosphates injection from patient care areas.

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Neuromuscular Blocking Agent Labelling and Packaging Initiative

A collaborative meeting of representatives of pharmaceutical manufacturers of neuromuscular blocking agents was convened by ISMP Canada in Toronto on February 27th, 2006. The foremost outcome was agreement among the attending stakeholders on the "ideal features" for packaging and labeling of neuromuscular blocking agents:

1. Red cap with white lettering: "Paralyzing agent" or "Warning: Paralyzing Agent"
2. Red ferrule with white lettering: "Paralyzing agent"
3. Red lettering on the product label: "Paralyzing agent" or "Warning: Paralyzing Agent"
4. Peel-off label, using the colour scheme and content information recognized by the ASA/CAS recommended standards, for application to a prepared syringe (ASA = American Society of Anesthesiologists (www.asahq.org); CAS = Canadian Anesthesiologists' Society (www.cas.ca)
5. Space on the product label for bar code application
6. Development of a universal symbol for neuromuscular blocking agents and proposal for global use: placement of this symbol (e.g., on the label), to be determined
7. Review of potential benefit of using TALL-man lettering for generic names of neuromuscular blocking agents

Participating manufacturers (Sandoz Inc, Hospira, Organon, and Abbott) are evaluating the feasibility of incorporating some or all of these features.

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To report a medication error to ISMP Canada: (i) visit our website www.ismp-canada.org, or (ii) e-mail us at info@ismp-canada.org, or (iii) phone us at 416-480-4099. ISMP Canada guarantees confidentiality and security of information received. ISMP Canada respects the wishes of the reporter as to the level of detail to be included in our publications.

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