



PHYSICIANS' DESK REFERENCE®

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PRODUCT INFORMATION

INDICATIONS

For the temporary relief of these hay fever and other upper respiratory allergy symptoms: sneezing, itchy watery eyes, nasal congestion, sore throat, runny nose, itchy throat and stuffy nose.

DIRECTIONS

All doses may be repeated every 4-6 hours. Do not use more than 4 times in 24 hours. Under 6 years (under 48 lb), consult a physician. An Accudose™ measuring cup is provided for accurate dosing. **Children's TYLENOL® ALLERGY-Liquid** 6-11 years (48-95 lbs): 2 teaspoonfuls.

WARNINGS

Do not use if plastic carton is broken, bottle wrap, or foil inner seal imprinted "Safety Seal®" is broken or missing. Do not take for pain for more than 5 days or for fever for more than 3 days unless directed by a doctor. If pain or fever persists, or gets worse, if new symptoms occur, or if redness or swelling is present, consult a doctor because these could be signs of a serious condition. Do not exceed recommended dosage. If nervousness, dizziness or sleeplessness occur, discontinue use and consult a doctor. Do not give this product to a child who has a breathing problem such as chronic bronchitis, or who has glaucoma, heart disease, high blood pressure, thyroid disease, or diabetes without first consulting the child's doctor. May cause marked drowsiness; sedatives and tranquilizers may increase the drowsiness effect. Do not give this product to children who are taking sedatives or tranquilizers without first consulting the child's doctor. Keep this and all drugs out of the reach of children. In case of accidental overdose, contact a doctor or poison control center immediately. Prompt medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms. Do not use with other products containing acetaminophen.

DRUG INTERACTION PRECAUTIONS

Do not give this product to a child who is taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric or blood pressure disorders), or for 2 weeks after stopping the MAOI drug. If you are uncertain whether your child's prescription drug contains an MAOI, consult a health professional before giving this product.

PROFESSIONAL INFORMATION

OVERDOSE INFORMATION

Acetaminophen in massive overdose may cause hepatic toxicity in some patients. In adults and adolescents, hepatic toxicity has rarely been reported following ingestion of acute overdose of less than 10 grams. Fatalities are infrequent (less than 3-4% of untreated cases) and have rarely been reported with overdoses of less than 15 grams. In children, an acute overdose of less than 150 mg/kg has not been associated with hepatic toxicity.

Early symptoms following a potentially hepatotoxic overdose may include nausea, vomiting, diaphoresis and general malaise. Clinical and laboratory evidence of hepatic toxicity has not been apparent until 48 to 72 hours postingestion. In adults and adolescents, regardless of the quantity of acetaminophen reported to have been ingested, administer acetylcysteine immediately if 24 hours or less have elapsed from the reported time of ingestion. For full prescribing information, refer to the acetylcysteine package insert. Do not await the results of assays for acetaminophen level before initiating treatment with acetylcysteine. The following additional procedures are recommended: The stomach should be emptied promptly by lavage or by induction of emesis with syrup of ipecac. A plasma acetaminophen assay should be obtained as early as possible, but no sooner than 4 hours following ingestion. Liver function studies should be obtained initially and repeated at 24-hour intervals. Serious toxicity or fatalities are extremely infrequent in children, possibly due to differences in the way they metabolize acetaminophen. In children, the maximum potential amount ingested can be more easily estimated. If more than 150 mg/kg or an unknown amount was ingested, obtain an acetaminophen plasma level. The acetaminophen plasma level should be obtained as soon as possible, but no sooner than 4 hours following the ingestion. Induce emesis using syrup of ipecac. If the plasma level is obtained and falls above the broken line on the acetaminophen overdose nomogram, the acetylcysteine therapy should be initiated and continued for a full course of therapy. If acetaminophen plasma assay capability is not available, and the estimated acetaminophen ingestion exceeds 150 mg/kg, acetylcysteine therapy should be initiated and continued for a full course of therapy.

For additional emergency information, call your regional poison center or call the Rocky Mountain Poison Center toll-free (1-800-525-6115).

Diphenhydramine toxicity should be treated as you would an antihistaminic/anticholinergic overdose and it is likely to be present within a few hours after acute ingestion. Symptoms from pseudoephedrine overdose consist most often of mild anxiety, tachycardia and/or mild hypertension. Symptoms usually appear within 4 to 8 hours of ingestion and are transient usually requiring no treatment.

INACTIVE INGREDIENTS

Benzoic Acid, Citric Acid, Corn Syrup, Flavors, Polyethylene Glycol, Propylene Glycol, Sodium Benzoate, Sorbitol, Purified Water, Red #33, Red #40.

HOW SUPPLIED

Pinkish-red colored liquid in child resistant bottles of 4 fl. oz. Shown in Product Identification Guide, page 321.

Children's TYLENOL® acetaminophen Chewable Tablets, Elixir, Suspension Liquid and Suspension Drops

OTC

DESCRIPTION

Infants' TYLENOL® Grape Suspension Drops are stable, alcohol-free, grape-flavored and purple in color. **Infants' TYLENOL® Cherry Suspension Drops** are stable, alcohol-free, cherry-flavored and red in color. Each 0.8 mL (one calibrated dropperful) contains 80 mg acetaminophen. **Children's TYLENOL® Elixir** is stable and alcohol-free, cherry-flavored, and red in color. **Children's TYLENOL® Suspension Liquid** is stable, alcohol-free, cherry-flavored, and red in color, or bubble gum flavored, and pink in color or grape flavored and purple in color. Each 5 mL (one teaspoonful) contains 160 mg acetaminophen. Each **Children's TYLENOL® Chewable Tablet** contains 80 mg acetaminophen in a grape, bubble gum, or fruit burst flavor.

ACTIONS

Acetaminophen is a clinically proven analgesic/antipyretic. Acetaminophen produces analgesia by elevation of the pain threshold and antipyretic through action on the hypothalamic heat regulating center. Acetaminophen is equal to aspirin in analgesic and antipyretic effectiveness and it is unlikely to produce many of the side effects associated with aspirin and aspirin-containing products.

INDICATIONS

Children's TYLENOL® Chewable Tablets, Elixir, Suspension Liquid and Suspension Drops are designed for treatment of infants and children with conditions requiring temporary relief of fever and discomfort due to colds and "flu," and of simple pain and discomfort due to teething, immunizations and tonsillitis.

Precautions:

If a rare sensitivity reaction occurs, the drug should be stopped.

DIRECTIONS

All dosages may be repeated every 4 hours, but not more than 5 times daily. Under 2 years (under 24 lb), consult a physician. **Children's TYLENOL® Chewable Tablets** 2-3 years (24-35 lb): 2 tablets; 4-5 years (36-47 lb): 3 tablets; 6-8 years (48-59 lb): 4 tablets; 9-10 years (60-71 lb): 5 tablets; 11 years (72-95 lb): 6 tablets. **Children's TYLENOL® Elixir & Suspension Liquid**: Measuring cup is provided for accurate dosing. 2-3 years (24-35 lb): 1 1/2 teaspoonfuls; 4-5 years (36-47 lb): 1 1/2 teaspoonfuls; 6-8 years (48-59 lb): 2 teaspoonfuls; 9-10 years (60-71 lb): 2 1/2 teaspoonfuls; 11 years (72-95 lb): 3 teaspoonfuls. **Infants' TYLENOL® Suspension Drops**: A calibrated dropper is provided for accurate dosing. 2-3 years (24-35 lb): 2 dropperfuls (2 x 0.8 mL). Professional Dosage Schedule: **Children's TYLENOL® Elixir & Suspension Liquid** 4-11 months (11-17 lb): 1/2 teaspoonful; 12-23 months (18-23 lb): 1/2 teaspoonful. **Infants' TYLENOL® Suspension Drops** 3-3 months (6-11 lb): 0.4 mL; 4-11 months (12-17 lb): 0.8 mL; 12-23 months (18-23 lb): 1.2 mL. All dosages may be repeated every 4 hours, but not more than 5 times daily.

WARNINGS

Do not take for pain more than 5 days or for fever for more than 3 days unless directed by a physician. If pain or fever persists or gets worse, if new symptoms occur, or if redness or swelling is present, consult a physician because these could be signs of a serious condition. Keep this and all drugs out of the reach of children. In case of accidental overdose, contact a physician or poison control center immediately. Prompt medical attention is critical even if you do not notice any signs or symptoms. Do not use with other products containing acetaminophen.

NOTE: In addition to the above:

Infants' TYLENOL® Suspension Drops: Do not use if printed carton overwrap or printed plastic Safety Seal® is broken or missing.

Children's TYLENOL® Elixir and Suspension Liquid: Do not use if plastic carton wrap, or seal imprinted "Safety Seal®" is broken or missing. Do not use if printed plastic bottle wrap or printed foil inner seal is broken. Not a USP elixir. **Children's TYLENOL® Chewable Tablets**: Do not use if carton is opened or if printed neck wrap of printed foil inner

seal is broken. Phenylethanolamines: grape contains phenylethanolamine 3 mg per tablet; bubble gum contains 6 mg per tablet, fruit burst contains 4.5 mg per tablet.

PROFESSIONAL INFORMATION

OVERDOSE INFORMATION

Acetaminophen in massive overdose may cause hepatic toxicity in some patients. In adults and adolescents, hepatic toxicity has rarely been reported following ingestion of acute overdoses of less than 10 grams. Fatalities are infrequent (less than 3-4% of untreated cases) and have rarely been reported with overdoses of less than 15 grams. In children, an acute overdose of less than 150 mg/kg has not been associated with hepatic toxicity. Early symptoms following a potentially hepatotoxic overdose may include nausea, vomiting, diaphoresis and general malaise. Clinical and laboratory evidence of hepatic toxicity has not been apparent until 48 to 72 hours postingestion.

In adults and adolescents, regardless of the quantity of acetaminophen reported to have been ingested, administer acetylcysteine immediately if 24 hours or less have elapsed from the reported time of ingestion. For full prescribing information, refer to the acetylcysteine package insert. Do not await the results of assays for acetaminophen level before initiating treatment with acetylcysteine. The following additional procedures are recommended: The stomach should be emptied promptly by lavage or by induction of emesis with syrup of ipecac. A serum acetaminophen assay should be obtained as early as possible, but no sooner than 4 hours following ingestion. Liver function studies should be obtained initially and repeated at 24-hour intervals.

Serious toxicity or fatalities are extremely infrequent in children, possibly due to differences in the way they metabolize acetaminophen. In children, the maximum potential amount ingested can be more easily estimated. If more than 150 mg/kg or an unknown amount was ingested, obtain an acetaminophen plasma level. The acetaminophen plasma level should be obtained as soon as possible, but no sooner than 4 hours following the ingestion. Induce emesis using syrup of ipecac. If the plasma level is obtained and falls above the broken line on the acetaminophen overdose nomogram, the acetylcysteine therapy should be initiated and continued for a full course of therapy. If acetaminophen plasma assay capability is not available, and the estimated acetaminophen ingestion exceeds 150 mg/kg, acetylcysteine therapy should be initiated and continued for a full course of therapy.

For additional emergency information, call your regional poison center or call the Rocky Mountain Poison Center toll-free (1-800-525-6115).

INACTIVE INGREDIENTS

Children's TYLENOL® Fruit Burst Flavored Chewable Tablets: Aspartame, Cellulose, Citric Acid, Corn Starch, Flavors, Magnesium Stearate, Mannitol, Red #7, may contain Ethylcellulose or Cellulose Acetate and Povidone.

Children's TYLENOL® Grape Flavored Chewable Tablets: Aspartame, Cellulose, Citric Acid, Corn Starch, Flavors, Magnesium Stearate, Mannitol, Blue #1, Red #7, and Red #30, may contain Ethylcellulose or Cellulose Acetate and Povidone.

Children's TYLENOL® Bubble Gum Flavored Chewable Tablets: Aspartame, Cellulose, Flavors, Gum Arabic, Magnesium Stearate, Maltodextrin, Mannitol, and Red #7, may contain Ethylcellulose or Cellulose Acetate and Povidone. **Children's TYLENOL® Elixir**: Benzoic Acid, Citric Acid, Flavors, Glycerin, Polyethylene Glycol, Propylene Glycol, Sodium Benzoate, Sorbitol, Sucrose, Purified Water, Red #33, Red #40.

Children's TYLENOL® Suspension Liquid: Butylparaben, Cellulose, Citric Acid, Corn Syrup, Flavors, Glycerin, Propylene Glycol, Purified Water, Sodium Benzoate, Sorbitol, Xanthan Gum. In addition to the above ingredients there is also FD&C Red #40. **Infants' TYLENOL® Grape Suspension Drops**: Butylparaben, Cellulose, Citric Acid, Corn Syrup, Flavors, Glycerin, Propylene Glycol, Purified Water, Sodium Benzoate, Sorbitol, Xanthan Gum, D&C Red #33, and FD&C Blue #1.

HOW SUPPLIED
Chewable Tablets (pink colored fruit, purple colored grape, pink colored bubble gum, and yellow colored "Fruit Burst"). Bottles of 30 and also blister packaged 60's (fruit burst). **Elixir** (cherry colored red); bottles of 2 and 4 fl. oz. **Suspension Liquid** (cherry colored red); bottles of 2 and 4 fl. oz. **Bubble gum flavored** contains pink and grape flavored colored.

Continued on next page

Consult 1998 PDR supplements and future editions for revisions

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Children's Tylenol—Cont.

purple): bottle of 4 fl. oz. Suspension drops (grape colored purple) bottles of $\frac{1}{2}$ oz. (15 mL) (cherry colored red): bottles of $\frac{1}{2}$ oz. and 1 oz. each with calibrated plastic dropper. All packages listed above have child-resistant safety caps or blisters.

Shown in Product Identification Guide, page 321

Children's TYLENOL[®] COLD OTC
Multi Symptom Chewable Tablets and Liquid**DESCRIPTION**

Each Children's **TYLENOL[®] COLD Multi Symptom Chewable Grape-Flavored Tablet** contains acetaminophen 80 mg, chlorpheniramine maleate 0.5 mg and pseudoephedrine hydrochloride 7.5 mg. **Children's TYLENOL[®] COLD Multi Symptom Liquid** is grape flavored and contains no alcohol. Each teaspoon (5 mL) contains acetaminophen 160 mg, chlorpheniramine maleate 1 mg, and pseudoephedrine hydrochloride 15 mg.

ACTIONS

Children's TYLENOL[®] COLD Multi Symptom Chewable Tablets and Liquid combines the analgesic-antipyretic acetaminophen with the decongestant pseudoephedrine hydrochloride and the antihistamine chlorpheniramine maleate to help relieve nasal congestion, dry runny nose, and prevent sneezing as well as to relieve the fever, aches, pains and general discomfort associated with colds and upper respiratory infections. Acetaminophen is equal to aspirin in analgesic and antipyretic effectiveness and it is unlikely to produce the side effects often associated with aspirin or aspirin-containing products.

INDICATIONS

For temporary relief of nasal congestion, runny nose, sore throat, sneezing, minor aches and pains, headaches and fever due to the common cold, hay fever or other upper respiratory allergies.

PRECAUTIONS

If a rare sensitivity reaction occurs, the drug should be stopped.

DIRECTIONS

All doses may be repeated every 4–6 hours, not to exceed 4 doses in 24 hours. Under 6 years (under 48 lbs), consult a physician. **Children's TYLENOL[®] COLD Chewable Tablets**: 6–11 years (48–95 lbs): 4 tablets. **Children's TYLENOL[®] COLD Liquid Formula**: An Accudose[™] measuring cup is provided and marked for accurate dosing: 6–11 years (48–95 lbs): 2 teaspoonsful.

Professional Dosing Schedule: **Children's TYLENOL[®] COLD Chewable Tablets**: 2–5 years (24–47 lbs): 2 tablets. **Children's TYLENOL[®] COLD Liquid**: 2–5 years (24–47 lbs): 1 teaspoonful. All doses may be repeated every 4–6 hours, not to exceed 4 doses in 24 hours.

WARNINGS

KEEP THIS AND ALL MEDICATION OUT OF THE REACH OF CHILDREN. IN CASE OF ACCIDENTAL OVERDOSE, CONTACT A PHYSICIAN OR POISON CONTROL CENTER IMMEDIATELY. PROMPT MEDICAL ATTENTION IS CRITICAL. EVEN IF YOU DO NOT NOTICE ANY SIGNS OR SYMPTOMS, DO NOT USE WITH OTHER PRODUCTS CONTAINING ACETAMINOPHEN. DO NOT EXCEED RECOMMENDED DOSAGE. Do not take for pain for more than 5 days or for fever for more than 3 days unless directed by a doctor. If pain or fever persists or get worse, if new symptoms occur, or if redness or swelling is present, consult a doctor because these could be signs of a serious condition. If sore throat is severe, persists for more than 3 days, is accompanied or followed by fever, headache, rash, nausea, or vomiting, consult a doctor promptly. If nervousness, dizziness, or sleeplessness, occur discontinue use and consult a doctor. May cause excitability especially in children. Do not give this product to children who have a breathing problem such as chronic bronchitis, or who have glaucoma, heart disease, high blood pressure, thyroid disease, or diabetes without first consulting the child's doctor. May cause drowsiness. Sedatives and tranquilizers may increase the drowsiness effect. Do not give this product to children who are taking sedatives or tranquilizers, without first consulting the child's doctor.

NOTE: In addition to the above:

Children's TYLENOL[®] COLD Chewable Tablets: DO NOT USE IF CARTON IS OPENED, OR IF PRINTED NECK WRAP OR PRINTED FOIL INNER SEAL IS BROKEN. **PHENYLEKETONURICS**: CONTAINS PHENYLALANINE 6 MG PER TABLET. **Children's TYLENOL[®] COLD Liquid**: DO NOT USE IF CARTON IS OPENED, OR IF PRINTED PLASTIC BOTTLE WRAP OR PRINTED FOIL INNER SEAL IS BROKEN.

Information will be superseded by supplements and subsequent editions

DRUG INTERACTION PRECAUTION

Do not give this product to a child who is taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric or emotional conditions, or for 2 weeks after stopping the MAOI drug. If you are uncertain whether your child's prescription drug contains an MAOI, consult a health professional before giving this product.

PROFESSIONAL INFORMATION
OVERDOSE INFORMATION

Acetaminophen in massive overdose may cause hepatic toxicity in some patients. In adults and adolescents, hepatic toxicity has rarely been reported following ingestion of acute overdoses of less than 10 grams. Fatalities are infrequent (less than 3–4% of untreated cases) and have rarely been reported with overdoses of less than 15 grams. In children, an acute overdose of less than 150 mg/kg has not been associated with hepatic toxicity.

Early symptoms following a potentially hepatotoxic overdose may include: nausea, vomiting, diaphoresis and general malaise. Clinical and laboratory evidence of hepatic toxicity may not be apparent until 48 to 72 hours postingestion.

In adults and adolescents, regardless of the quantity of acetaminophen reported to have been ingested, administer acetylcysteine immediately if 24 hours or less have elapsed from the reported time of ingestion. For full prescribing information, refer to the acetylcysteine package insert. Do not wait the results of assays for acetaminophen level before initiating treatment with acetylcysteine. The following additional procedures are recommended: The stomach should be emptied promptly by lavage or by induction of emesis with syrup of ipecac. A plasma acetaminophen assay should be obtained as early as possible, but no sooner than 4 hours following ingestion. Liver function studies should be obtained initially and repeated at 24-hour intervals.

Serious toxicity or fatalities are extremely infrequent in children, possibly due to differences in the way they metabolize acetaminophen. In children, the maximum potential amount ingested can be more easily estimated. If more than 150 mg/kg or an unknown amount was ingested, obtain a plasma acetaminophen level. The acetaminophen plasma level should be obtained as soon as possible, but no sooner than 4 hours following the ingestion. Induce emesis using syrup of ipecac. If the plasma level is obtained and falls above the broken line on the acetaminophen overdose nomogram, the acetylcysteine therapy should be initiated and continued for a full course of therapy. If acetaminophen plasma assay capability is not available, and the estimated acetaminophen ingestion exceeds 150 mg/kg, acetylcysteine therapy should be initiated and continued for a full course of therapy.

For additional emergency information, call your regional poison center or call the Rocky Mountain Poison Center toll-free, (1-800-525-6115).

Chlorpheniramine toxicity should be treated as you would an antihistaminic/anticholinergic overdose and is likely to be present within a few hours after acute ingestion. Symptoms from pseudoephedrine overdose consist most often of mild anxiety, tachycardia and/or mild hypertension. Symptoms usually appear within 4 to 8 hours of ingestion and are transient, usually requiring no treatment.

INACTIVE INGREDIENTS

Chewable Tablets: Aspartame, Basic Polymethacrylate, cellulose acetate, citric acid, flavors, hydroxypropyl methylcellulose, magnesium stearate, mannitol, microcrystalline cellulose, Blue #1, Red #7. **Liquid**: Benzoic acid, citric acid, flavors, glycerin, maleic acid, polyethylene glycol, propylene glycol, sodium benzoate, sorbitol, sucrose, purified water, Blue #1 and Red #40.

HOW SUPPLIED

Chewable Tablets (colored purple, scored, imprinted "Tylenol C" on one side and "TC" on opposite side—Blisters of 24 Liquid Formula—bottle of colored purple of 4 fl. oz.—Blisters of 24)

Shown in Product Identification Guide, page 321

Children's TYLENOL[®] OTC
COLD Multi Symptom
PLUS COUGH Chewable Tablets and Liquid**DESCRIPTION**

Each **Children's TYLENOL[®] COLD Multi Symptom Plus Cough Chewable Cherry-Flavored Tablet** contains acetaminophen 80 mg, chlorpheniramine maleate 0.5 mg, dextromethorphan hydrobromide 2.5 mg, and pseudoephedrine hydrochloride 7.5 mg.

Children's TYLENOL[®] COLD Multi Symptom Plus Cough Liquid is cherry flavored and contains no alcohol. Each teaspoon (5 mL) contains acetaminophen 160 mg, chlorpheniramine maleate 1 mg, dextromethorphan hydrobromide 5 mg and pseudoephedrine hydrochloride 15 mg.

ACTIONS

Children's TYLENOL[®] COLD Multi Symptom Plus Cough Chewable Tabletand **Liquid** combine an analgesic-antipyretic acetaminophen with the decongestant pseudoephedrine hydrochloride, the cough suppressant dextromethorphan hydrobromide, and the antihistamine chlorpheniramine maleate to help relieve coughs, nasal congestion, and sore throat, dry runny noses, and prevent sneezing as well as to relieve the fever, aches, pains and general discomfort associated with colds and upper respiratory infections. Acetaminophen is equal to aspirin in analgesic and antipyretic effectiveness and it is unlikely to produce the side effects often associated with aspirin or aspirin-containing products.

INDICATIONS

For temporary relief of coughs, nasal congestion, runny nose, sore throat, sneezing, minor aches and pains, headaches and fever due to the common cold, hay fever, or other upper respiratory allergies.

PRECAUTION

If a rare sensitivity reaction occurs, the drug should be stopped.

DIRECTIONS

All doses may be repeated every 4–6 hours, not to exceed 4 doses in 24 hours. Under 6 years (under 48 lbs), consult a physician.

Children's TYLENOL[®] COLD Multi Symptom Plus Cough Chewable Tablets: 6–11 years (48–95 lbs): 4 tablets. **Children's TYLENOL[®] COLD Multi Symptom Plus Cough Liquid**: An Accudose[™] measuring cup is provided and marked for accurate dosing: 6–11 years (48–95 lbs): 2 teaspoonsful.

Professional Dosing Schedule: **Children's TYLENOL[®] COLD Multi Symptom Plus Cough Chewable Tablets**: 2–5 years (24–47 lbs): 2 tablets. **Children's TYLENOL[®] COLD Multi Symptom Plus Cough Liquid**: 2–5 years (24–47 lbs): 1 teaspoonful. All doses may be repeated every 4–6 hours, not to exceed 4 doses in 24 hours.

WARNINGS

KEEP THIS AND ALL MEDICATION OUT OF THE REACH OF CHILDREN. IN CASE OF ACCIDENTAL OVERDOSE, CONTACT A DOCTOR OR POISON CONTROL CENTER IMMEDIATELY. PROMPT MEDICAL ATTENTION IS CRITICAL. EVEN IF YOU DO NOT NOTICE ANY SIGNS OR SYMPTOMS, DO NOT USE WITH OTHER PRODUCTS CONTAINING ACETAMINOPHEN. DO NOT EXCEED RECOMMENDED DOSAGE. Do not take for pain for more than 5 days or for fever for more than 3 days unless directed by a doctor. If pain or fever persists or get worse, if new symptoms occur, or if redness or swelling is present, consult a doctor because these could be signs of a serious condition. If sore throat is severe, persists for more than 3 days, is accompanied or followed by fever, headache, rash, nausea or vomiting, consult a doctor promptly. If nervousness, dizziness, or sleeplessness occur, discontinue use and consult a doctor. May cause excitability especially in children. Do not give this product to children who have a breathing problem such as chronic bronchitis, or who have glaucoma, heart disease, high blood pressure, thyroid disease, or diabetes without first consulting the child's doctor. May cause drowsiness. Sedatives and tranquilizers may increase the drowsiness effect. Do not give this product to children who are taking sedatives or tranquilizers, without first consulting the child's doctor. A persistent cough may be a sign of a serious condition. If cough persists for more than 1 week, tends to recur, or is accompanied by fever, rash or persistent headache, consult a doctor. Do not give this product for persistent or chronic cough such as occurs with asthma or if cough is accompanied by acute pharyngeal (throat) muscle spasms (croup).

NOTE: In addition to the above:

Chewable Tablets: DO NOT USE IF CARTON IS OPENED, OR IF PRINTED NECK WRAP OR PRINTED FOIL INNER SEAL IS BROKEN. **PHENYLEKETONURICS**: CONTAINS PHENYLALANINE 4 MG PER TABLET. **Liquid**: DO NOT USE IF CARTON IS OPENED, OR IF PRINTED PLASTIC BOTTLE WRAP OR PRINTED FOIL INNER SEAL IS BROKEN.

DRUG INTERACTION PRECAUTION

Do not give this product to a child who is taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric or emotional conditions, or for 2 weeks after stopping the MAOI drug. If you are uncertain whether your child's prescription drug contains an MAOI, consult a health professional before giving this product.

PROFESSIONAL INFORMATION
OVERDOSE INFORMATION

Acetaminophen in massive overdose may cause hepatic toxicity in some patients. In adults and adolescents, hepatic toxicity has rarely been reported following ingestion of acute overdoses of less than 10 grams. Fatalities are infrequent (less than 3–4% of untreated cases) and have rarely

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been reported with overdoses of less than 15 grams. In children, an acute overdose of less than 150 mg/kg has not been associated with hepatic toxicity. Early symptoms following a potentially hepatotoxic overdose may include: nausea, vomiting, diarrhea and general malaise. Clinical and laboratory evidence of hepatic toxicity may not be apparent until 48 to 72 hours post-ingestion.

In adults and adolescents, regardless of the quantity of acetaminophen reported to have been ingested, administer acetylcysteine immediately if 24 hours or less have elapsed from the reported time of ingestion. If plasma level information, refer to the acetylcysteine package insert. Do not await the results of assays for plasma acetaminophen level before initiating treatment with acetylcysteine. The following additional procedures are recommended: The stomach should be emptied promptly by lavage or by induction of emesis with syrup of ipecac. A plasma acetaminophen assay should be obtained as early as possible, but no sooner than four hours following ingestion. If plasma level falls above the lower treatment line on the acetaminophen overdose nomogram, acetylcysteine therapy should be continued. Liver function studies should be obtained initially and repeated at 24-hour intervals.

Serious toxicity or fatalities are extremely infrequent in children, possibly due to differences in the way they metabolize acetaminophen. In children, the maximum potential amount ingested can be more easily estimated. If more than 150 mg/kg or an unknown amount was ingested, obtain an plasma acetaminophen level. The plasma acetaminophen level should be obtained as soon as possible, but no sooner than 4 hours following the ingestion. If plasma level falls above the lower treatment line on the acetaminophen overdose nomogram, the acetylcysteine therapy should be initiated and continued for a full course of therapy. If plasma acetaminophen assay capability is not available, and the estimated acetaminophen ingestion exceeds 150 mg/kg, acetylcysteine therapy should be initiated and continued for a full course of therapy.

For additional emergency information, call your regional poison center or call the Rocky Mountain Poison Center toll-free, 1-800-525-6115. Chlorpheniramine toxicity should be treated as you would an antihistamine/anticholinergic overdose and is likely to be present within a few hours after acute ingestion.

Symptoms from pseudoephedrine overdose usually consist of mild anxiety, tachycardia and/or mild hypertension. Symptoms usually appear within 4 to 8 hours of ingestion and are transient, usually requiring no treatment. Acute dextromethorphan overdose usually does not result in serious signs and symptoms unless massive amounts have been ingested. Signs and symptoms of a substantial overdose may include nausea and vomiting, visual disturbances, CNS disturbances, and urinary retention.

INACTIVE INGREDIENTS

Cheewable Tablets: Aspartame, Basic Polyethacrylate, Cellulose Acetate, Colloidal Silicon Dioxide, Flavors, Hydroxypropyl Methylcellulose, Mannitol, Microcrystalline Cellulose, Stearic Acid and Red #7. **Liquid:** Citric Acid, Corn Syrup, Flavors, Polyethylene Glycol, Propylene Glycol, Sodium Benzoate, Sodium Carboxymethyl Cellulose, Sorbitol, Purified Water, Red #33 and Red #40.

HOW SUPPLIED

Cheewable Tablets (colored pink, imprinted "TYLENOL®" on one side and "TCO" on the opposite side)—Blister Packs of 24. **Liquid Formulation** (red colored) bottles of 4 fl. oz.

Shown in Product Identification Guide, page 321

Children's
TYLENOL® FLU
Liquid

OTC

DESCRIPTION

Children's TYLENOL® FLU Liquid is bubble-gum flavored and contains no alcohol or aspirin. Each teaspoon (5 mL) contains acetaminophen 160 mg, pseudoephedrine HCl 15 mg, dextromethorphan HBr 7.5 mg, and chlorpheniramine maleate 1 mg.

ACTIONS

Children's TYLENOL® FLU Liquid combines the analgesic/antipyretic acetaminophen with the decongestant pseudoephedrine hydrochloride, the cough suppressant dextromethorphan hydrobromide and the antihistamine chlorpheniramine maleate to provide fast, effective, temporary relief of all your child's symptoms associated with flu including fever, body aches, headache, stuffy nose, runny nose, sore throat and cough.

Acetaminophen is equal to aspirin in analgesic and antipyretic effectiveness and it is unlikely to produce the side effects often associated with aspirin or aspirin-containing products.

INDICATIONS

For the temporary relief of fever, minor aches and pains, headaches, sore throat, nasal congestion, runny nose and coughs due to a cold or "flu".

DIRECTIONS

All doses may be repeated every 6-8 hours. Not to exceed 4 doses in 24 hours. Under 6 years (under 48 lbs), consult a physician. An Accudose® measuring cup is provided for accurate dosing. **Children's TYLENOL® FLU Liquid** 6-11 years (48-95 lbs): 2 teaspoons. Professional Dose Schedule: 2-5 years (24-47 lbs): 1 teaspoonful. All doses may be repeated every 6-8 hours. Not to exceed 4 doses in 24 hours.

WARNINGS

DO NOT USE IF PLASTIC CARTON WRAP, BOTTLE WRAP, OR FOIL INNER SEAL IMPRINTED "SAFETY SEAL" IS BROKEN OR MISSING. KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN. IN CASE OF ACCIDENTAL OVERDOSE, CONTACT DOCTOR OR POISON CONTROL CENTER IMMEDIATELY. PROMPT MEDICAL ATTENTION IS CRITICAL FOR ADULTS AS WELL AS CHILDREN EVEN IF YOU DO NOT NOTICE ANY SIGNS OR SYMPTOMS. DO NOT USE WITH OTHER PRODUCTS CONTAINING ACETAMINOPHEN. DO NOT EXCEED RECOMMENDED DOSAGE. Do not take for pain for more than 5 days or for fever for more than 3 days unless directed by a doctor. If pain or fever persists, or gets worse, if new symptoms occur, or if redness or swelling is present, consult a doctor because these could be signs of a serious condition. If sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, nausea or vomiting, consult a doctor promptly. A persistent cough may be a sign of a serious condition. If cough persists for more than 1 week, tends to worsen or is accompanied by fever, rash, or persistent headache, consult a doctor. Do not give this product for persistent or chronic cough such as occurs with asthma, or if cough is accompanied by excessive phlegm or is otherwise directed by a doctor. If nervousness, dizziness or sleeplessness occur, discontinue use and consult a doctor. May cause excitability especially in children. Do not give this product to children who have a breathing problem such as chronic bronchitis, or who have glaucoma, heart disease, high blood pressure, thyroid disease or diabetes without first consulting the child's doctor. If you notice drowsiness, sedation and/or tranquilization may increase the drowsiness effect. Do not give this product to children who are taking sedatives or tranquilizers under doctor's supervision.

DRUG INTERACTION PRECAUTION

Do not give the time product to a child who is taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you are uncertain whether your child's prescription drug contains an MAOI, consult a health professional before giving this product.

PROFESSIONAL INFORMATION

OVERDOSEAGE INFORMATION

Acetaminophen in massive overdoses may cause hepatic toxicity in some patients. In adults and adolescents, hepatic toxicity has rarely been reported following ingestion of acute overdoses of less than 10 grams. Fatalities are infrequent (less than 3-4% of untreated cases) and have rarely been reported with overdoses of less than 15 grams. In children, an acute overdose of less than 150 mg/kg has not been associated with hepatic toxicity. Early symptoms following a potentially hepatotoxic overdose may include: nausea, vomiting, diarrhea and general malaise. Clinical and laboratory evidence of hepatic toxicity may not be apparent until 48 to 72 hours post-ingestion.

In adults and adolescents, regardless of the quantity of acetaminophen reported to have been ingested, administer acetylcysteine immediately if 24 hours or less have elapsed from the reported time of ingestion. For full prescribing information, refer to the acetylcysteine package insert. Do not await the results of assays for plasma acetaminophen level before initiating treatment with acetylcysteine. The following additional procedures are recommended: The stomach should be emptied promptly by lavage or by induction of emesis with syrup of ipecac. A plasma acetaminophen assay should be obtained as early as possible, but no sooner than four hours following ingestion. If plasma level falls above the lower treatment line on the acetaminophen overdose nomogram, acetylcysteine therapy should be continued. Liver function studies should be obtained initially and repeated at 24-hour intervals.

Serious toxicity or fatalities are extremely infrequent in children, possibly due to differences in the way they metabolize acetaminophen. In children, the maximum potential amount ingested can be more easily estimated. If more than 150 mg/kg or an unknown amount was ingested, obtain an plasma acetaminophen level. The plasma acetaminophen level should be obtained as soon as possible, but no sooner

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than 4 hours following the ingestion. If plasma level falls above the lower treatment line on the acetaminophen overdose nomogram, the acetylcysteine therapy should be initiated and continued for a full course of therapy. If plasma acetaminophen assay capability is not available, and the estimated acetaminophen ingestion exceeds 150 mg/kg, acetylcysteine therapy should be initiated and continued for a full course of therapy.

For additional emergency information, call your regional poison center or call the Rocky Mountain Poison Center toll-free, 1-800-525-6115.

Chlorpheniramine toxicity should be treated as you would an antihistamine anticholinergic overdose and is likely to be present within a few hours after acute ingestion. Symptoms from pseudoephedrine overdose consist most often of mild anxiety, tachycardia, and/or mild hypertension. Symptoms usually appear within 4 to 8 hours of ingestion and are transient, usually requiring no treatment.

Acute dextromethorphan overdose usually does not result in serious signs and symptoms unless massive amounts have been ingested. Signs and symptoms of a substantial overdose may include nausea and vomiting, visual disturbances, CNS disturbances, and urinary retention.

INACTIVE INGREDIENTS

Citric Acid, Corn Syrup, Flavors, Polyethylene Glycol, Propylene Glycol, Purified Water, Sodium Benzoate, Sodium Carboxymethyl Cellulose, Sorbitol, Red #33 and Red #40.

HOW SUPPLIED

Pinkish-red colored liquid in child resistant bottles of 4 fl. oz.

Shown in Product Identification Guide, page 321

Children's TYLENOL®
SINUS Liquid

OTC

DESCRIPTION

Children's TYLENOL® SINUS Liquid is fruit flavored and contains no alcohol or aspirin. Each teaspoon (5 mL) contains acetaminophen 160 mg and pseudoephedrine HCl 15 mg.

ACTIONS

Children's TYLENOL® SINUS Liquid combines the analgesic/antipyretic acetaminophen with the decongestant pseudoephedrine hydrochloride to provide fast, effective, temporary relief of all your child's sinus symptoms including stuffy nose, sinus headache, sinus pressure, sinus pain and nasal congestion. Acetaminophen is equal to aspirin in analgesic and antipyretic effectiveness and is unlikely to produce the side effects often associated with aspirin or aspirin-containing products.

INDICATIONS

For the temporary relief of minor aches, pains and headaches, sinus congestion, stuffy nose, and sinus pressure.

DIRECTIONS

All doses may be repeated every 4-6 hours. Do not use more than 4 times in 24 hours. Under 2 years (under 24 lbs), consult a physician. An Accudose® measuring cup is provided for accurate dosing. **Children's TYLENOL® SINUS Liquid** 2-5 years (24-47 lbs): 1 teaspoonful; 6-11 years (48-95 lbs): 2 teaspoonfuls.

WARNINGS

DO NOT USE IF PLASTIC CARTON WRAP, BOTTLE WRAP, OR FOIL INNER SEAL IMPRINTED "SAFETY SEAL" IS BROKEN OR MISSING. DO NOT USE FOR PAIN FOR MORE THAN 5 DAYS OR FOR FEVER FOR MORE THAN 3 DAYS UNLESS DIRECTED BY A DOCTOR. IF PAIN OR FEVER PERSISTS, OR GETS WORSE, IF NEW SYMPTOMS OCCUR, OR IF REDNESS OR SWELLING IS PRESENT, CONSULT A DOCTOR BECAUSE THESE COULD BE SIGNS OF A SERIOUS CONDITION. DO NOT EXCEED RECOMMENDED DOSAGE. If nervousness, dizziness or sleeplessness occur, discontinue use and consult a doctor. Do not give this product to children who have a breathing problem such as chronic bronchitis, or who have glaucoma, heart disease, high blood pressure, thyroid disease, or diabetes without first consulting the child's doctor. Keep this and all drugs out of the reach of children. In case of accidental overdose, contact a doctor or poison control center immediately. Prompt medical attention is critical for adults as for children even if you do not notice any signs or symptoms. Do not use with other products containing acetaminophen.

DRUG INTERACTION PRECAUTION

Do not give this product to a child who is taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric or emotional conditions), or for 2 weeks after stopping the MAOI drug. If you are uncertain whether your child's prescription drug contains an MAOI, consult a health professional before giving this product.

Continued on next page

Consult 1998 PDR® supplements and future editions for revisions

KINDERFARMS Ex. 1018
KINDERFARMS LLC. v. GENEXA INC.
POR23-33-051

Children's Tylenol Sinus—Cont.**PROFESSIONAL INFORMATION****OVERDOSAGE INFORMATION**

Acetaminophen in massive overdose may cause hepatic toxicity in some patients. In adults and adolescents, hepatic toxicity has rarely been reported following ingestion of acute overdose of less than 10 grams. Fatalities are infrequent (less than 3-4% of untreated cases) and have rarely been reported with overdoses of less than 15 grams. In children an acute overdose of less than 150 mg/kg has not been associated with hepatic toxicity.

Early symptoms following a potentially hepatotoxic overdose may include: nausea, vomiting, diaphoresis and general malaise. Clinical and laboratory evidence of hepatic toxicity may not be apparent until 48 to 72 hours post-ingestion. In adults and adolescents, regardless of the quantity of acetaminophen reported to have been ingested, administer acetylcysteine immediately if 24 hours or less have elapsed from the reported time of ingestion. For full prescribing information, refer to the acetylcysteine package insert. Do not await the results of assays for acetaminophen level before initiating treatment with acetylcysteine. The following additional procedures are recommended: The stomach should be emptied promptly by lavage or by induction of emesis with syrup of ipecac. A plasma acetaminophen assay should be obtained as early as possible, but no sooner than 4 hours following ingestion. Liver function studies should be obtained initially and repeated at 24-hour intervals. Serious toxicity or fatalities are extremely infrequent in children, possibly due to differences in the way they metabolize acetaminophen. In children, the maximal potential amount ingested can be more easily estimated. If more than 150 mg/kg or an unknown amount was ingested, obtain an plasma acetaminophen level. The acetaminophen plasma level should be obtained as soon as possible, but no sooner than 4 hours following the ingestion. Induce emesis using syrup of ipecac. If the plasma level is obtained and falls above the broken line on the acetaminophen overdose nomogram, the acetylcysteine therapy should be initiated and continued for a full course of therapy. If acetaminophen plasma assay capability is not available, and the estimated acetaminophen ingestion exceeds 150 mg/kg, acetylcysteine therapy should be initiated and continued for a full course of therapy.

For additional emergency information, call your regional poison center or call the Rocky Mountain Poison Center toll-free, (1-800-526-6115).

Symptoms from pseudophedrine overdose consist most often of mild anxiety, tachycardia and/or mild hypertension. Symptoms usually appear within 4 to 8 hours of ingestion and are transient, usually requiring no treatment.

INACTIVE INGREDIENTS

Ascesulfate Potassium, Benzoic Acid, Citric Acid, Corn Syrup, Flavors, Polyethylene Glycol, Propylene Glycol, Sodium Benzoate, Sorbitol, Purified Water, Red #3, Red #40.

HOW SUPPLIED

Red colored liquid in child resistant bottles 4 oz.

Shown in Product Identification Guide, page 321

MODUM® A-D

(loperamide hydrochloride)

OTC

DESCRIPTION

Each 5 mL (teaspoon) of **MODUM® A-D** liquid contains loperamide hydrochloride 1 mg. **MODUM® A-D** liquid is stable, cherry-mint flavored, and clear in color.

Each caplet of **MODUM® A-D** contains 2 mg of loperamide and is scored and colored green.

ACTIONS

MODUM® A-D contains a clinically proven antidiarrheal medication. Loperamide HCl acts by slowing intestinal motility and by affecting water and electrolyte movement through the bowel.

INDICATIONS

MODUM® A-D is indicated for the control and symptomatic relief of acute nonspecific diarrhea, including Traveler's Diarrhea.

DIRECTIONS

Adults and children 12 years of age and older: Take four teaspoonfuls or two caplets after first loose bowel movement. If needed, take two teaspoonfuls or one caplet after each subsequent loose bowel movement. Do not exceed eight teaspoonfuls or four caplets in any 24 hour period, unless directed by a physician.

Children 6-11 years old (60-95 lbs.): Two teaspoonfuls or one caplet after first loose bowel movement, followed by one teaspoonful or one-half caplet after each subsequent loose bowel movement. Do not exceed six teaspoonfuls or three caplets a day.

Information will be superseded by supplements and subsequent editions

Children 6-8 years old (48-59 lbs.): Two teaspoonfuls or one caplet after first loose bowel movement, followed by one teaspoonful or one-half caplet after each subsequent loose bowel movement. Do not exceed four teaspoonfuls or two caplets a day.

Professional Dosage Schedule for children 2-5 years old (24-47 lbs.): One teaspoon after first loose bowel movement, followed by one after each subsequent loose bowel movement. Do not exceed three teaspoonfuls a day.

WARNINGS

KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN. Do not use for more than two days unless directed by a physician. **DO NOT USE IF DIARRHEA IS ACCOMPANIED BY HIGH FEVER (GREATER THAN 101°F), OR IF BLOOD OR MUCUS IS PRESENT IN THE STOOL, OR IF YOU HAVE HAD A RASH OR OTHER ALLERGIC REACTION TO LOPERAMIDE HCl.** If you are taking antacids or have a history of liver disease, consult a physician before using this product. As with any drug, if you are pregnant or nursing a baby, seek the advice of a health professional before using this product. In case of accidental overdose, seek professional assistance or contact a poison control center immediately.

PROFESSIONAL INFORMATION**OVERDOSAGE INFORMATION**

Overdose of loperamide HCl in man may result in constipation, CNS depression and nausea. A slurry of activated charcoal administered promptly after ingestion of loperamide hydrochloride can reduce the amount of drug which is absorbed. If vomiting occurs spontaneously upon ingestion, a slurry of 100 grams of activated charcoal should be administered orally as soon as fluids can be retained. If vomiting has not occurred, and CNS depression is evident, gastric lavage should be performed followed by administration of 100 tubes of the activated charcoal slurry through the gastric tube. In the event of overdose, patients should be monitored for signs of CNS depression for at least 24 hours. Children may be more sensitive to central nervous system effects than adults. If CNS depression is observed, naloxone may be administered. If responsive to naloxone, vital signs must be monitored carefully for recurrence of symptoms drug overdose for at least 24 hours after the last dose of naloxone.

INACTIVE INGREDIENTS

Liquid: Benzoic acid, citric acid, flavors, glycerin, propylene glycol, purified water, sodium benzoate, sorbitol, sucrose, contains 0.5% alcohol.

Caplets: Dibasic calcium phosphate, magnesium stearate, microcrystalline cellulose, colloidal silicon dioxide, FD&C Blue #1 and D&C Yellow #10.

HOW SUPPLIED

Cherry-mint flavored liquid (clear) 2 fl. oz., and 4 fl. oz. tamper evident bottles with child resistant safety caps and special dosage caps.

Green Scored caplets in 6's and 12's, 18's and 24's blister packaging which is tamper evident and child resistant.

Shown in Product Identification Guide, page 321

Infants' TYLENOL® COLD

Decongestant & Fever Reducer Drops

OTC

DESCRIPTION

Infants' TYLENOL® COLD Decongestant & Fever Reducer Drops are alcohol-free, bubble gum flavored and red in color. Each 0.8 mL (drop) contains acetaminophen 80 mg and pseudophedrine HCl 7.5 mg.

ACTIONS

Acetaminophen is a clinically proven analgesic/antipyretic. Acetaminophen produces analgesia by elevation of the pain threshold and antipyresis through action on the hypothalamic heat regulating center. Acetaminophen is equal to aspirin in analgesic and antipyretic effectiveness and it is unlikely to produce many of the side effects associated with aspirin and aspirin containing products. Pseudophedrine hydrochloride is a sympathomimetic amine which provides temporary relief of nasal congestion.

INDICATIONS

Infants' TYLENOL® COLD Decongestant & Fever Reducer Drops are indicated for the temporary relief of nasal congestion, minor aches and pains, headaches and fever due to the common cold, hay fever or other upper respiratory allergies.

PRECAUTIONS

If a rare sensitivity reaction occurs, the drug should be stopped.

DIRECTIONS

All dosages may be repeated every 4-6 hours, but not more than 4 times daily. Under 2 years (under 24 lbs.), consult a physician. A calibrated dropper is provided for accurate dosing.

Infants' TYLENOL® COLD Decongestant & Fever Reducer Drops: 2-3 years old (24-35 lbs.): 2 drops (0.4 x 0.8 mL). Professional Dosage Schedule: 0-3 months of age: 0.4 mL; 4-11 months (12-17 lbs): 0.8 mL; 12-23 months (22 lbs): 1.2 mL. All dosages may be repeated every 4-6 hours, but not more than 4 times daily.

WARNINGS

Do not use if printed carton overwrap or printed plastic bottle wrap is broken or missing or if carton is opened. **Keep this and all medication out of the reach of children.** In case of accidental overdose, contact a doctor or poison control center immediately. Prompt medical attention is critical even if you do not notice any signs or symptoms. Do not exceed recommended dosage. Do not use for more than 5 days or for fever for more than 3 days unless directed by a doctor. If pain or fever persists or gets worse, if new symptoms occur, or if redness or swelling is present, consult a doctor because these could be signs of a serious condition. If nervousness, dizziness or sleeplessness occur, discontinue use and consult a doctor. Do not give this product to a child who has heart disease, high blood pressure, thyroid disease, or diabetes unless directed by a doctor. Do not use with other products containing acetaminophen.

DRUG INTERACTION PRECAUTION

Do not give this product to a child who is taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric or emotional conditions) and for 2 weeks after stopping the MAOI drug. If you are uncertain whether your child is taking a MAOI drug, consult an MAOI health professional before giving this product.

PROFESSIONAL INFORMATION**OVERDOSAGE INFORMATION**

Acetaminophen in massive overdose may cause hepatic toxicity in some patients. In adults and adolescents, hepatic toxicity has rarely been reported following ingestion of acute overdoses of less than 10 grams. Fatalities are infrequent (less than 3-4% of untreated cases) and have rarely been reported with overdoses of less than 15 grams. In children, an acute overdose of less than 150 mg/kg has not been associated with hepatic toxicity.

Early symptoms following a potentially hepatotoxic overdose may include: nausea, vomiting, diaphoresis and general malaise. Clinical and laboratory evidence of hepatic toxicity may not be apparent until 48 to 72 hours post-ingestion. In adults and adolescents, regardless of the quantity of acetaminophen reported to have been ingested, administer acetylcysteine immediately if 24 hours or less have elapsed from the reported time of ingestion. For full prescribing information, refer to the acetylcysteine package insert. Do not await the results of assays for acetaminophen level before initiating treatment with acetylcysteine. The following additional procedures are recommended: The stomach should be emptied promptly by lavage or by induction of emesis with syrup of ipecac. A plasma acetaminophen assay should be obtained as early as possible, but no sooner than 4 hours following ingestion. If plasma level falls above the lower treatment line on the acetaminophen overdose nomogram, the acetylcysteine therapy should be initiated and continued for a full course of therapy. If plasma acetaminophen level is obtained and falls above the broken line on the acetaminophen overdose nomogram, the acetylcysteine therapy should be initiated and continued for a full course of therapy. If acetaminophen plasma assay capability is not available, and the estimated acetaminophen ingestion exceeds 150 mg/kg, acetylcysteine therapy should be initiated and continued for a full course of therapy.

For additional emergency information, call your regional poison center or call the Rocky Mountain Poison Center toll-free, (1-800-526-6115).

Symptoms from pseudophedrine overdose consist most often of mild anxiety, tachycardia and/or mild hypertension. Symptoms usually appear within 4 to 8 hours of ingestion and are transient, usually requiring no treatment.

INACTIVE INGREDIENTS

Citric Acid, Corn Syrup, Flavors, Polyethylene Glycol, Propylene Glycol, Purified Water, Sodium Benzoate, Saccharin, FD&C Red #40.

HOW SUPPLIED

Red-colored drops in bottles of 1/2 fl. oz.

Shown in Product Identification Guide, page 321

KINDERFARMS Ex. 078
KINDERFARMS LLC, v. GENEXA INC.
PGR2023-0051