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Silvergate Pharmaceuticals Release: FDA Approves XATMEP, The First and Only Ready-To-Use Methotrexate Oral Solution

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DENVER, April 26, 2017 /PRNewswire/ -- Silvergate Pharmaceuticals, Inc. (www.silvergatepharma.com), leaders in the development and commercialization of innovative and safe medicines for children, today announced that the United States Food and Drug Administration (FDA) approved XATMEP (methotrexate) Oral Solution, the first and only FDA-approved methotrexate oral solution. XATMEP is indicated for the treatment of acute lymphoblastic leukemia (ALL) and polyarticular juvenile idiopathic arthritis (pJIA) in pediatric patients.

"XATMEP is an exciting product in that it provides an FDA-approved, ready-to-use oral solution of methotrexate for children without the need for needles, crushing of tablets or compounding into a liquid formulation," said Frank Segrave, President & CEO, Silvergate Pharmaceuticals, Inc. "*As a company, we continue to focus on pediatric medications that are safe, effective, and readily available."*

XATMEP (methotrexate) Oral Solution, 2.5 mg/mL, is a ready-to-use product that requires no preparation, facilitating accuracy and ease of dispensing at the pharmacy. XATMEP is manufactured under CGMPs in accordance with FDA regulations. It eliminates the need for needles, crushing or

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extensive network of pharmacies and a qualified mail-order service. For additional information on how to obtain XATMEP, please call 1-855-379-0382.

INDICATIONS

XATMEP is a folate analog metabolic inhibitor indicated for the:

management of pediatric patients with active polyarticular juvenile idiopathic arthritis (pJIA) who have had an insufficient therapeutic response to, or are intolerant of, an adequate trial of first-line therapy including full dose non-steroidal anti-inflammatory agents (NSAIDs).
treatment of pediatric patients with acute lymphoblastic leukemia (ALL) as part of a multi-phase, combination chemotherapy maintenance regimen.

About XATMEP

XATMEP (methotrexate) Oral Solution was developed, primarily, to meet the need for a ready-to-use, 2.5 mg/mL, methotrexate oral solution for the treatment of pediatric patients for the indications stated above. Currently, there is no FDA-approved, ready-to-use oral liquid formulation of methotrexate for use by pediatric patients requiring body surface area (BSA) dosing (mg/m^2) or who have difficulty swallowing or cannot consume tablets, or those with needle-phobia. Silvergate Pharmaceuticals, Inc.'s XATMEP (methotrexate) Oral Solution resolves these unmet medical needs in pediatric patients.

IMPORTANT SAFETY INFORMATION

XATMEP includes a BOXED WARNING: SEVERE TOXIC REACTIONS, INCLUDING EMBRYO-FETAL TOXICITY

See full prescribing information for complete boxed warning.

Methotrexate can cause severe or fatal toxicities. Monitor closely and modify dose or discontinue for the following toxicities: bone marrow suppression (5.1), infection (5.2), renal (5.3), gastrointestinal (5.4), hepatic (5.5), pulmonary (5.6), hypersensitivity and dermatologic (5.7).

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XATMEP and risks to the fetus when prescribing XATMEP to a pregnant patient with a neoplastic disease. Advise patients to use effective contraception during and after treatment with XATMEP (5.9, 8.1, 8.3).

ADDITIONAL IMPORTANT SAFETY INFORMATION

XATMEP is contraindicated in patients who are hypersensitive to methotrexate.
XATMEP is contraindicated in patients who are pregnant or nursing.

Warnings and Precautions:

Monitor closely and modify dose or discontinue XATMEP as appropriate.

Methotrexate can cause the following severe, life-threatening or fatal adverse reactions:

Bone marrow suppression: pancytopenia, anemia, leukopenia, neutropenia, and thrombocytopenia.
Serious infections: bacterial, fungal, or viral infections, including *Pneumocystis jiroveci* pneumonia, invasive fungal, hepatitis B reactivation, tuberculosis, *Herpes zoster* and cytomegalovirus infections.
Renal toxicity and renal impairment, including acute renal failure.
Gastrointestinal toxicity: diarrhea, stomatitis, vomiting, hemorrhagic enteritis, fatal intestinal perforation. Unexpected severe and fatal gastrointestinal toxicity can occur with concomitant us of NSAIDs.
Hepatic toxicity: severe and potentially irreversible hepatotoxicity, including fibrosis, cirrhosis, and fatal liver failure.
Pulmonary toxicity: acute or chronic interstitial pneumonitis and irreversible or fatal cases at all dose levels.
Hypersensitivity: anaphylaxis.
Dermatologic reactions: toxic epidermal necrolysis, Stevens-Johnson syndrome, exfoliative dermatitis, skin necrosis, erythema multiforme. Radiation dermatitis and "sunburn" may be recalled.
Secondary malignancies: lymphoproliferative disease has been reported with low-dose oral methotrexate which regressed when methotrexate is withdrawn.
Embryo-fetal toxicity and fetal death: Consider the risks and benefits of XATMEP and risks to the fetus when prescribing to a pregnant patient with a neoplastic disease. XATMEP is contraindicated in non-neoplastic disease.

Effects on reproduction: Methotrexate can cause impairment of fertility, oligospermia, and menstrual dysfunction. Effective contraception should be practiced by patients of reproductive potential while receiving XATMEP therapy, and for 3 and 6 months afterwards for males and females, respectively.
Third-space accumulation: Evacuate significant third-space accumulation prior to methotrexate administrations.
Concomitant radiation therapy increases the risk of soft tissue necrosis and osteonecrosis associated with methotrexate.
Closely monitor laboratory parameters for hematology, renal function and liver function. Increase monitoring during initial dosing, dose changes and during periods of increased risk of elevated methotrexate blood levels (e.g., dehydration).
Improper dosing: Once weekly dosing is appropriate. Fatal toxicity has been reported with daily dosing. An accurate millimeter measuring device should be used.
Advise women not to breastfeed.

Adverse Reactions: **See full prescribing information for additional adverse reactions.**

Most common adverse reactions are ulcerative stomatitis, leukopenia, nausea, abdominal distress, and elevated liver function tests.

Other frequently reported reactions are malaise, fatigue, chills and fever, dizziness, and decreased risk to infection.

Drug Interactions:

Oral antibiotics: Hematologic and gastrointestinal toxicity may increase.
Hepatotoxins: May increase hepatoxicity.
Probenecid: Consider alternative drugs as may increase methotrexate exposure.
Theophylline: May reduce theophylline clearance.

To report SUSPECTED ADVERSE REACTIONS, contact Silvergate Pharmaceuticals at 1-855-379-0383, or FDA at 1-800-FDA-1088 or www.fda.gov/MedWatch.

Please see accompanying full Prescribing Information, including the complete BOXED WARNING.

pharmaceutical company dedicated to leading the way in the development and commercialization of innovative pediatric medications that are safe, effective, and readily available.

Silvergate Pharmaceuticals is committed to filling the unmet needs of children, developing innovative medications that will help improve the quality of care and outcomes for pediatric patients. For more information, please visit http://www.silvergatepharma.com.

Reference: XATMEP [prescribing information]. Greenwood Village, CO: Silvergate Pharmaceuticals, Inc.; 2017.

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Read more news from Silvergate Pharmaceuticals, Inc.

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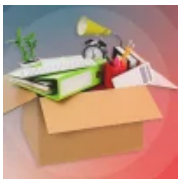

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