For Immediate Release

August, 2018

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American Regent Announces the Launch and Availability of Fomepizole Injection, AP Rated and Therapeutically Equivalent to Antizol®*[1]

Shirley, NY - American Regent today announced the launch and availability of Fomepizole Injection, AP rated and therapeutically equivalent to Antizol®.

Fomepizole Injection is indicated as an antidote for ethylene glycol (such as antifreeze) or methanol poisoning, or for use in suspected ethylene glycol or methanol ingestion, either alone or in combination with hemodialysis.

Fomepizole Injection must be diluted prior to use. For intravenous use only.

Fomepizole Injection will be available in a 1 g/mL, 1.5 mL preservative free Single Dose Vial and can be ordered through wholesalers/distributors.

Fomepizole Injection is supplied as follows:

NDC#	Strength	Supplied As	Shelf Pack
0517-0710-01	1 g/mL	1.5 mL Single Dose Vial	1

*Antizol® is a registered trademark of Paladin Labs Inc.

See the following Important Safety Information in addition to the Full Prescribing Information.

Reference: 1. Approved Drug Products with Therapeutic Equivalence Evaluations.
https://www.accessdata.fda.gov/scripts/cder/ob/results_product.cfm?Appl_Type=A&Appl_No=078368 Accessed July 2018

Fomepizole Injection

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INDICATIONS AND USAGE
Fomepizole Injection is indicated as an antidote for ethylene glycol (such as antifreeze) or methanol poisoning, or for use in suspected ethylene glycol or methanol ingestion, either alone or in combination with hemodialysis.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS
Fomepizole Injection should not be administered to patients with a documented serious hypersensitivity reaction to Fomepizole Injection or other pyrazoles.

PRECAUTIONS
General: Fomepizole Injection should not be given undiluted or by bolus injection.

Minor allergic reactions have been reported. Patients should be monitored for signs of allergic reactions.

Laboratory Tests: Monitor patient throughout the treatment.

Pregnancy: Pregnancy Category C: Fomepizole should be given to pregnant women only if clearly needed.

Nursing Mothers: Caution should be exercised when fomepizole is administered to a nursing woman.

Pediatric and Geriatric Use: Safety and effectiveness have not been established.

ADVERSE REACTIONS
The most frequent adverse events reported as drug-related or unknown relationship to study drug who received Fomepizole Injection were headache (14%), nausea (11%), and dizziness, increased drowsiness, and bad taste/metallic taste (6% each). All other adverse events in this population were reported in approximately 3% or fewer of those receiving fomepizole and were as follows:

Body as a Whole: Abdominal pain, fever, multiorgan system failure, pain during fomepizole injection, inflammation at injection site, lumbalgia/backache, hangover

Cardiovascular: Sinus bradycardia/bradycardia, phlebosclerosis, tachycardia, phlebitis, shock, hypotension

Gastrointestinal: Vomiting, diarrhea, dyspepsia, heartburn, decreased appetite, transient transaminitis

Hemic/Lymphatic: Eosinophilia/hypereosinophilia, lymphangitis, disseminated intravascular coagulation, anemia

Nervous: Lightheadedness, seizure, agitation, feeling drunk, facial flush, vertigo, nystagmus, anxiety, “felt strange”, decreased environmental awareness

Respiratory: Hiccups, pharyngitis

Skin/Appendages: Application site reaction, rash

Special Senses: Abnormal smell, speech/visual disturbances, transient blurred vision, roar in ear

Urogenital: Anuria

USE IN SPECIAL POPULATIONS
Fomepizole Injection has not been studied sufficiently to determine whether the pharmacokinetics differ for geriatric and pediatric populations and between genders.

Renal Insufficiency: The metabolites of fomepizole are excreted renally. Definitive pharmacokinetic studies have not been done to assess pharmacokinetics in patients with renal impairment.

Hepatic Insufficiency: Fomepizole is metabolized through the liver, but no definitive pharmacokinetic studies have been done in subjects with hepatic disease.

OVERDOSAGE
Nausea, dizziness, and vertigo were noted in healthy volunteers receiving 3 to 6 times the recommended dose. This dose-dependent CNS effect was short-lived in most subjects and lasted up to 30 hours in one subject. Fomepizole is dialyzable, and hemodialysis may be useful in treating cases of overdosage.

For additional Safety Information, please see Full Prescribing Information.

You are encouraged to report Adverse Drug Events (ADEs) to American Regent:
Email: pv@luitpold.com; Fax: 1-610-650-0170; Phone: 1-800-734-9236

ADEs may also be reported to the FDA at 1-800-FDA-1088 or to **www.fda.gov/Medwatch**

Drug Information:
1-888-354-4855 (9:00 am - 5:00 pm Eastern Time, Monday - Friday)
1-877-845-6371 (Available outside of normal business hours)

About American Regent
American Regent is a leader in the development, manufacturing and sales of generic and branded IV products. With a history of 50 years in generic specialty injectables, American Regent has sales approaching one billion dollars.

American Regent strives for continuous improvement to bring to market high quality innovative medications to meet unmet medical needs, and produces high quality accessible generic medications covering a wide array of therapeutic areas. American Regent is a member of the Daiichi Sankyo Group; and is headquartered in Shirley, NY.

For more information, please visit americanregent.com.

About Daiichi Sankyo
Daiichi Sankyo is a global pharmaceutical company with corporate origins in Japan. We provide innovative products and services in more than 20 countries around the world. With more than 100 years of scientific expertise, our company draws upon a rich legacy of innovation and a robust pipeline of promising new medicines to help patients.

Through the outstanding knowledge and commitment of our 15,000 employees worldwide, we create innovative new and generic medicines, and new methods of drug discovery and delivery. We share a passion for innovation, as well as compassion for the patients around the world who are in need of our medicines.

For more information, please visit: www.daiichisankyo.com. Daiichi Sankyo, Inc., headquartered in Basking Ridge, New Jersey, is a member of the Daiichi Sankyo Group. For more information on Daiichi Sankyo, Inc., please visit: www.dsi.com.