American Regent Launches FDA-Approved Atropine Sulfate Injection, USP

Atropine Sulfate Injection, USP, is supplied as a 1 mL single dose vial with a strength of 0.4 mg/mL and 1 mg/mL.

Melville, NY – August 9, 2022: American Regent, Inc. has announced the launch of Atropine Sulfate Injection, USP, a longstanding injectable medication, now with FDA approval. Atropine Sulfate Injection, USP, is indicated for temporary blockade of severe or life-threatening muscarinic effects, e.g., as an antisialagogue, an antivagal agent, an antidote for organophosphorus, or muscarinic mushroom poisoning, and to treat bradyasystolic cardiac arrest.

American Regent is committed to gaining approval for each of our previously marketed-unapproved products, and has dedicated significant effort to gaining approval for Atropine. "We are proud to add Atropine to our extensive line of FDA-approved injectables, most of which are formulated, filled and finished here in the US," said Joann Gioia, Vice President and Chief Commercial Officer. "With the FDA's approval, we are pleased to be able to reliably supply this critical IV treatment to patients who need it."

This product is available for immediate shipment. Customers can order Atropine Sulfate Injection, USP, through their wholesaler/distributor, or by contacting our Customer Support Group at 1-800-645-1706.

Atropine Sulfate Injection, USP, is supplied as follows:

Pack NDC#	Strength	Supplied as	Shelf pack
0517-1004-25	0.4 mg/mL	1 mL Single-dose vial	25
0517-1001-25	1 mg/mL	1 mL Single-dose vial	25

See the following Important Safety Information, in addition to the product's Full Prescribing Information.

For additional information, please visit www.americanregent.com.

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A Daiichi Sankyo Group Company

Atropine Sulfate Injection, USP

For intravenous use

INDICATIONS AND USAGE

Atropine Sulfate Injection, USP, is indicated for temporary blockade of severe or life-threatening muscarinic effects, e.g., as an antisialagogue, an antivagal agent, an antidote for organophosphorus or muscarinic mushroom poisoning, and to treat bradyasystolic cardiac arrest.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

None

WARNINGS AND PRECAUTIONS

Tachycardia: When the recurrent use of atropine is essential in patients with coronary artery disease, the total dose should be restricted to 2 to 3 mg (max 0.03 to 0.04 mg/kg) to avoid the detrimental effects of atropine-induced tachycardia on myocardial oxygen demand.
Acute Glaucoma: Atropine may precipitate acute glaucoma.
Pyloric Obstruction: Atropine may convert partial organic pyloric stenosis into complete obstruction.
Complete Urinary Retention: Atropine may lead to complete urinary retention in patients with prostatic hypertrophy.
Viscid Plugs: Atropine may cause inspissation of bronchial secretions and formation of viscid plugs in patients with chronic lung disease.

ADVERSE REACTIONS

Most of the side effects of atropine are directly related to its antimuscarinic action. Dryness of the mouth, blurred vision, photophobia and tachycardia commonly occur. Anhidrosis can produce heat intolerance. Constipation and difficulty in micturition may occur in elderly patients. Hypersensitivity reactions have been observed.

DRUG INTERACTIONS

Mexiletine: Atropine Sulfate Injection decreased the rate of mexiletine absorption.

USE IN SPECIFIC POPULATIONS

Pregnancy: It is not known whether atropine can cause fetal harm when given to a pregnant woman or can affect reproduction capacity.
Nursing Mothers: Trace amounts of atropine were found in breast milk. The clinical impact is not known.
Pediatric Use: Recommendations for use in pediatric patients are not based on clinical trials.
Geriatric Use: Dose selection for an elderly patient should be cautious.

OVERDOSAGE

The fatal adult dose of atropine is not known. In pediatric populations, 10 mg or less may be fatal.
Atropine is not removed by dialysis.

Pharmacokinetics – Specific Populations
The elimination half-life of atropine is more than doubled in children under two years and the elderly (>65 years old) compared to other age groups.

For additional safety information, please see the Full Prescribing Information.

You are encouraged to report adverse drug events to American Regent, Inc. at 1-800-734-9236, or to the FDA by visiting www.fda.gov/medwatch or calling 1-800-FDA-1088.

You are encouraged to report adverse drug events (ADEs) to American Regent:
T 1.800.734.9236; **E** pv@americanregent.com; **F** 1.610.650.0170

ADEs may also be reported to the FDA:
1.800.FDA.1088
or www.fda.gov/medwatch

Medical information:
T 1.888.354.4855 (9:00 am–5:00 pm Eastern Time, Monday–Friday)
www.americanregent.com/medical-affairs

For medical information outside of normal business hours
that cannot wait until the next business day, please call 1.877.845.6371

About American Regent
American Regent, Inc., a Daiichi Sankyo Group company, is a leading injectable manufacturer. For over 50 years, American Regent has been developing, manufacturing and supplying quality generic and branded injectables for healthcare providers. For nearly 20 years, we have been a leader in IV iron therapy.

American Regent is committed to US-based manufacturing. To that end, over the last several years, we have made significant investments in expanding and modernizing our manufacturing facilities in Ohio and New York. This expansion will nearly double our capacity and allow us to better serve our customers now and in the future.

Speed counts. Flexibility matters. Reliability and quality are paramount. Because patients should never have to wait for the medications they need.

For more information, please visit www.americanregent.com.

About Daiichi Sankyo Group
Daiichi Sankyo is dedicated to creating new modalities and innovative medicines by leveraging our world-class science and technology for our purpose "to contribute to the enrichment of quality of life around the world." In addition to our current portfolio of medicines for cancer and cardiovascular disease, Daiichi Sankyo is primarily focused on developing novel therapies for people with cancer as well as other diseases with high unmet medical needs. With more than 100 years of scientific expertise and a presence in more than 20 countries, Daiichi Sankyo and its 16,000 employees around the world draw upon a rich legacy of innovation to realize our 2030 Vision to become an "Innovative Global Healthcare Company Contributing to the Sustainable Development of Society." 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