Newly Launched Product

Atropine Sulfate Injection, USP

Benefits and Features

- Not made with natural rubber latex, DEHP, or PVC
- No Preservatives
- AP rated
- Luer Lock syringe compatible with Luer-Activated IV Systems
- Labeled over-pouch packaging takes less space in crash carts/ADMs
- Bar Coded

Product Information

UoS† NDC	Product #	Fill Volume	Concentration (mg/mL)	Content	Unit / BX	Bar Coded
64253-0400-91	40091	10 mL	0.1 mg/mL	1 mg/10 mL	10	√

Wholesalers Item Number

AmerisourceBergen	Cardinal Health	McKesson Drug	McKesson MedSurg	Morris & Dickson
10278983	5839824	2696144	1231706	274100

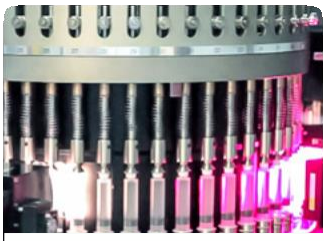
To learn more about Medefil's Atropine Sulfate Injection, USP please visit our website at www.medefilinc.com, call (630) 682-4600, or via email at: info@medefilinc.com

Atropine Sulfate Injection, USP

About Medefil

Medefil is growing as a fully integrated specialty pharmaceutical company. At Medefil our goal is to develop and manufacture injectable products where quality and supply reliability are crucial, and safety and ease-of use are of utmost importance. Medefil has a state-of-the-art scientific research infrastructure and high-quality manufacturing capabilities leading to effective execution of development and product supply.

State-of-the-art Manufacturing



Inspection

Labeling

Packaging

Important Safety Information

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 (maximum 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.

DRUG INTERACTIONS:

Atropine Sulfate Injection decreased the rate of mexiletine absorption without altering the relative oral bioavailability; this delay in mexiletine absorption was reversed by the combination of atropine and intravenous metoclopramide during pretreatment for anesthesia.

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. Occasional hypersensitivity reactions have been observed, especially skin rashes which in some instances progressed to exfoliation.

OVERDOSAGE:

Excessive dosing may cause palpitation, dilated pupils, difficulty in swallowing, hot dry skin, thirst, dizziness, restlessness, tremor, fatigue and ataxia. Toxic doses lead to restlessness and excitement, hallucinations, delirium and coma. Depression and circulatory collapse occur only with severe intoxication. In such cases, blood pressure declines and death due to respiratory failure may ensue following paralysis and coma.

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

In the event of toxic overdosage, a short acting barbiturate or diazepam may be given as needed to control marked excitement and convulsions. Large doses for sedation should be avoided because central depressant action may coincide with the depression occurring late in atropine poisoning. Central stimulants are not recommended.

Physostigmine, given as an atropine antidote by slow intravenous injection of 1 to 4 mg (0.5 to 1 mg in pediatric populations), rapidly abolishes delirium and coma caused by large doses of atropine. Since physostigmine is rapidly destroyed, the patient may again lapse into coma after one to two hours, and repeated doses may be required.

Artificial respiration with oxygen may be necessary. Ice bags and alcohol sponges help to reduce fever, especially in pediatric populations.

Atropine is not removed by dialysis.

To report SUSPECTED ADVERSE REACTIONS, contact Medefil, Inc. at 1-630-682-4600 or www.medefilinc.com or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

For complete prescribing information, refer to the package insert.

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