

**ATROPINE SULFATE- atropine sulfate ointment
AvPAK**

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

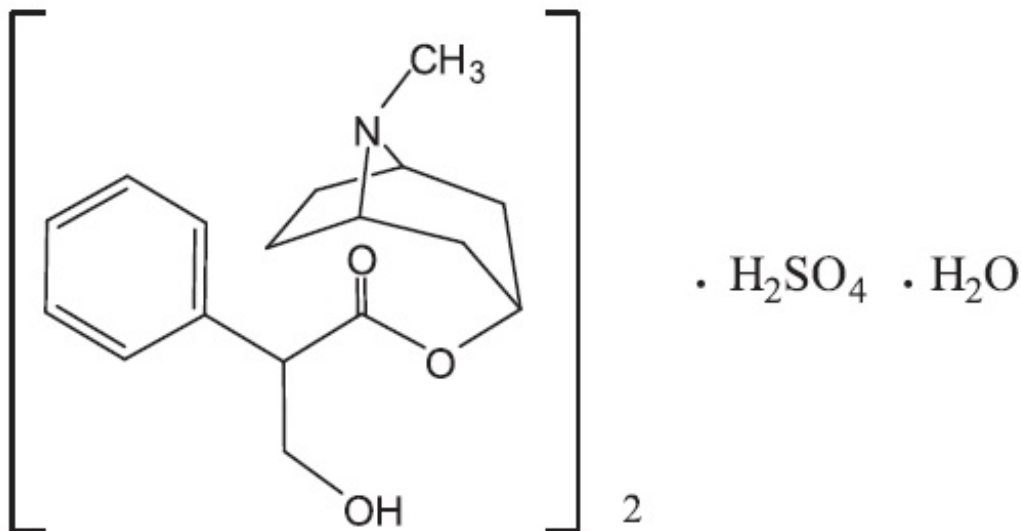
Atropine Sulfate

Ophthalmic Ointment, 1% (Sterile)

Rx only

DESCRIPTION:

Atropine Sulfate Ophthalmic Ointment, 1% is a sterile topical anticholinergic for ophthalmic use. The active ingredient is represented by the chemical structural formula:



$(\text{C}_{17}\text{H}_{23}\text{NO}_3)_2 \cdot \text{H}_2\text{SO}_4 \cdot \text{H}_2\text{O}$
Mol. Wt. 694.83

Chemical Name:

Benzeneacetic acid, α -(hydroxymethyl)-, 8-methyl-8-azabicyclo-[3.2.1]oct-3-yl ester, *endo*-(\pm)-, sulfate (2:1) (salt), monohydrate.

Each gram contains:

ACTIVE: Atropine Sulfate, 1% (10 mg); **INACTIVES:** Lanolin oil, mineral oil, purified water, and white petrolatum.

CHEMICAL PHARMACOLOGY

The anticholinergic effect of this product blocks the responses of the sphincter muscle of the iris and the accommodative muscle of the ciliary body to cholinergic stimulation, producing pupillary dilation (mydriasis) and paralysis of accommodation (cycloplegia).

INDICATIONS AND USAGE

For mydriasis and/or cycloplegia. For cycloplegic refraction, for pupillary dilation desired in inflammatory conditions of the iris and uveal tract.

CONTRAINDICATIONS

This product should not be used in patients with primary glaucoma or a predisposition to narrow anterior chamber angle glaucoma.

This product should not be used in pediatric patients who have previously had a severe systemic reaction to atropine. This product should not be used in those persons showing hypersensitivity to any component of this preparation.

WARNINGS

In pediatric patients, use with extreme caution. Excessive use in pediatric patients or in certain individuals with a previous history of susceptibility to belladonna alkaloids may produce systemic symptoms of atropine poisoning. If this occurs, discontinue medication and use appropriate therapy as outlined in OVERDOSAGE.

PRECAUTIONS

To avoid excessive systemic absorption, the lacrimal sac should be compressed by digital pressure for two to three minutes after instillation. To avoid inducing angle closure glaucoma, an estimation of the depth of the angle of the anterior chamber should be made. Administration of atropine in infants requires great caution.

Patient Warning:

Patients should be advised not to drive or engage in other hazardous activities while pupils are dilated. Patients may experience sensitivity to light and should protect eyes in bright illumination during dilation.

Parents should be warned not to get this preparation in their children's mouth and to wash their own hands and the child's hands following administration.

Carcinogenesis, Mutagenesis, Impairment of Fertility:

No studies have been conducted in animals or in humans to evaluate the potential of

these effects.

Animal reproduction studies have not been performed with atropine. It is also not known whether atropine can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Atropine should be given to pregnant women only if clearly needed.

Pediatric Use:

See CONTRAINDICATIONS and WARNINGS.

ADVERSE REACTIONS

Prolonged use may produce local irritation characterized by follicular conjunctivitis, vascular congestion, edema, exudate, and an eczematoid dermatitis. Severe reactions are manifested by hypotension with progressive respiratory depression. Coma and death have been reported in the very young.

To report SUSPECTED ADVERSE REACTIONS, contact AvKARE at 1-855-361-3993 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

OVERDOSAGE

Systemic atropine toxicity is manifested by flushing and dryness of the skin (a rash may be present in pediatric patients), blurred vision, a rapid and irregular pulse, fever, abdominal distension in infants, mental aberration (hallucinoses) and loss of neuromuscular coordination.

Atropine poisoning, although distressing, is rarely fatal, even with large doses of atropine, and is self-limited if the cause is recognized and the atropine medication is discontinued. In severe intoxication, physostigmine salicylate may be administered parenterally to provide more prompt relief of the intoxication. Give physostigmine salicylate as 1-5 mL IV of dilution containing 1 mg in 5 mL of saline. The smaller dose is for pediatric patients, and injection should take not less than 2 minutes. EKG control is advisable. Dosage can be repeated every 5 minutes up to a total dose of 2 mg in pediatric patients and 6 mg in adults every 30 minutes. Physostigmine is contraindicated in hypotensive reactions. Atropine (1 mg) should be available for immediate injection if physostigmine causes bradycardia, convulsions or bronchoconstriction. In pediatric patients, the body surface must be kept moist.

Use extreme caution when employing short-acting barbiturates to control excitement.

DOSAGE AND ADMINISTRATION

Apply a small amount of ointment to the conjunctival sac once or twice a day, or as directed by a physician.

FOR OPHTHALMIC USE ONLY

HOW SUPPLIED

Atropine Sulfate Ophthalmic Ointment, 1% is supplied in an ophthalmic tip applicator tube in the following size:

3.5 g tubes - NDC 50268-118-35

DO NOT USE IF CAP AND NECKRING ARE NOT INTACT.

STORAGE:

Store between 15° to 25°C (59° to 77°F).

Manufactured for:

AvKARE

Pulaski, TN 38478

AV 07/20

PACKAGE/LABEL PRINCIPAL DISPLAY PANEL

NON COATING AREA

NON COATING AREA

Each Gram Contains
Active: Atropine Sulfate,
 1% (10 mg);
Inactives: Lanolin oil,
 mineral oil, purified water,
 and white petrolatum.

Usual Dosage
 Apply a small amount of
 ointment to the conjunctival
 sac 1 or 2 times a day, or as
 directed by a physician.
 See package insert.

Warning
 Do not touch tube tip to
 any surface as this may
 contaminate the ointment.

NON COATING AREA
 1.40" X 1.34"

NON COATING AREA

**FOR OPHTHALMIC
 USE ONLY.**
 KEEP OUT OF REACH
 OF CHILDREN.
Storage
 Store between 15°-25°C
 (59°-77°F).

DO NOT USE IF CAP
 AND NECKRING
 ARE NOT INTACT.

Manufactured for:
 AvKARE
 Pulaski, TN 38478
 AV 07/20

AVKARE  3.5gm
**Atropine Sulfate
 Ophthalmic Ointment,
 1% (Sterile)**

NDC 50268-118-35
AVKARE
**Atropine
 Sulfate
 Ophthalmic
 Ointment,
 1% (Sterile)**

Rx only



1%



3.5gm

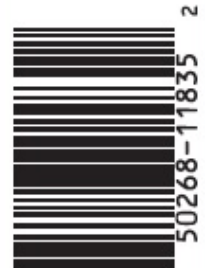
Net wt. 1/8 oz (3.5g)

AVKARE
**Atropine
 Sulfate
 Ophthalmic
 Ointment,
 1% (Sterile)**



1%

3.5gm



N 50268-11835 2

ATROPINE SULFATE

atropine sulfate ointment

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:50268-118
Route of Administration	OPHTHALMIC		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ATROPINE SULFATE (UNII: 03J5ZE7KA5) (ATROPINE - UNII:7C0697DR9I)	ATROPINE SULFATE	10 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
LANOLIN OIL (UNII: OVV5IJJ58F)	
MINERAL OIL (UNII: T5L8T28FGP)	
WATER (UNII: 059QF0KO0R)	
PETROLATUM (UNII: 4T6H12BN9U)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50268-118-35	1 in 1 CARTON	11/18/2020	
1		3.5 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		11/18/2020	

Labeler - AvPAK (832926666)

Revised: 1/2022

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