

# ATROPINE- atropine sulfate solution/ drops

## Redpharm Drug

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### HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use ATROPINE SULFATE OPHTHALMIC SOLUTION, safely and effectively. See full prescribing information for ATROPINE SULFATE OPHTHALMIC SOLUTION.

**ATROPINE SULFATE Ophthalmic Solution, 1% for topical ophthalmic use.**

**Initial U.S. Approval: 1960**

### INDICATIONS AND USAGE

Atropine is an anticholinergic agent indicated in adults and pediatric patients aged three (3) months and older for:

- Cycloplegia ( 1.1)
- Mydriasis ( 1.2)
- Penalization of the healthy eye in the treatment of amblyopia ( 1.3)

### DOSAGE AND ADMINISTRATION

- Apply 1 drop topically to the cul-de-sac of the conjunctiva, forty minutes prior to the intended maximal dilation time ( 2)
- In adults and pediatric patients 3 years and older, doses may be repeated up to twice daily as needed. ( 2)

### DOSAGE FORMS AND STRENGTHS

Ophthalmic solution 1% atropine sulfate ( 3)

### CONTRAINDICATIONS

Hypersensitivity or allergic reaction to any ingredient in formulation ( 4.1)

### WARNINGS AND PRECAUTIONS

- Photophobia and blurred vision due to pupil unresponsiveness and cycloplegia may last up to 2 weeks. ( 5.1)
- Risk of blood pressure increase from systemic absorption ( 5.2)

### ADVERSE REACTIONS

Most common adverse reactions that have been reported are eye pain and stinging on administration, blurred vision, photophobia, decreased lacrimation, increased heart rate and blood pressure. ( 6)

**To report SUSPECTED ADVERSE REACTIONS, contact Apotex Corp. at 1-800-706-5575 or FDA at 1-800-FDA-1088 or [www.fda.gov/medwatch](http://www.fda.gov/medwatch)**

### DRUG INTERACTIONS

The use of atropine and monoamine oxidase inhibitors (MAOI) is generally not recommended because of the potential to precipitate hypertensive crisis. ( 7)

### USE IN SPECIFIC POPULATIONS

Should only be used in pregnant women if clearly needed. ( 8)

**See 17 for PATIENT COUNSELING INFORMATION.**

**Revised: 9/2025**

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\* Sections or subsections omitted from the full prescribing information are not listed.

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## **FULL PRESCRIBING INFORMATION**

### **1. INDICATIONS AND USAGE**

Atropine sulfate ophthalmic solution, 1% is indicated in adults and pediatric patients aged three (3) months and older for:

#### **1.1 Cycloplegia**

#### **1.2 Mydriasis**

#### **1.3 Penalization of the Healthy Eye in the Treatment of Amblyopia**

### **2. DOSAGE AND ADMINISTRATION**

- Apply 1 drop topically to the cul-de-sac of the conjunctiva, forty minutes prior to the

intended maximal dilation time.

- In adults and pediatric patients aged 3 years and older, doses may be repeated up to twice daily as needed.

### **3. DOSAGE FORMS AND STRENGTHS**

Ophthalmic solution: 1% atropine sulfate.

### **4. CONTRAINDICATIONS**

#### **4.1 Hypersensitivity**

Atropine sulfate ophthalmic solution 1% is contraindicated in patients who have demonstrated a previous hypersensitivity or known allergic reaction to any ingredient of the formulation.

### **5. WARNINGS AND PRECAUTIONS**

#### **5.1 Photophobia and Blurred Vision**

Photophobia and blurred vision due to pupil unresponsiveness and cycloplegia may last up to 2 weeks.

#### **5.2 Elevation of Blood Pressure**

Elevations in blood pressure from systemic absorption has been reported following conjunctival instillation of recommended doses of atropine sulfate ophthalmic solution, 1%.

#### **5.3 Risk of Contamination**

Do not touch the dropper tip to the eye, eyelids, or any other surface as this may contaminate the solution.

### **6. ADVERSE REACTIONS**

The following serious adverse reactions are described below and elsewhere in the labeling:

- Photophobia and Blurred Vision [*See Warnings and Precautions ( 5.1)*]
- Elevation in Blood Pressure [*See Warnings and Precautions ( 5.2)*]

The following adverse reactions were identified in clinical studies or postmarketing reports following use of atropine sulfate ophthalmic solution. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

#### **6.1 Ocular Adverse Reactions**

Eye pain and stinging occurs upon instillation. Other commonly occurring adverse

reactions include, blurred vision, photophobia, superficial keratitis and decreased lacrimation. Allergic reactions such as papillary conjunctivitis, contact dermatitis, and lid edema may also occur less commonly.

## **6.2 Systemic Adverse Reactions**

Systemic effects of atropine are related to its anti-muscarinic activity. Systemic adverse events reported include dryness of skin, mouth, and throat from decreased secretions from mucus membranes; restlessness, irritability or delirium from stimulation of the central nervous system; tachycardia; flushed skin of the face and neck.

## **7. DRUG INTERACTIONS**

### **7.1 Monoamine Oxidase Inhibitors (MAOI)**

The use of atropine and monoamine oxidase inhibitors (MAOI) is generally not recommended because of the potential to precipitate hypertensive crisis.

## **8. USE IN SPECIFIC POPULATIONS**

### **8.1 Pregnancy**

#### Risk Summary

There are no adequate and well-controlled studies of atropine sulfate administration in pregnant women to inform a drug-associated risk. Adequate animal development and reproduction studies have not been conducted with atropine sulfate. In humans, 1% atropine sulfate is systemically bioavailable following topical ocular administration [see *Clinical Pharmacology* ( 12.3) ].

Atropine sulfate ophthalmic solution, 1% should only be used during pregnancy if the potential benefit justifies the potential risk to the fetus.

### **8.2 Lactation**

#### Risk Summary

There is no information to inform risk regarding the presence of atropine in human milk following ocular administration of atropine sulfate to the mother. The effects on breastfed infants and the effects on milk production are also unknown. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for atropine sulfate and any potential adverse effects on the breastfed child from atropine sulfate.

### **8.4 Pediatric Use**

The safety and effectiveness of Atropine Sulfate Ophthalmic Solution 1% have been established in pediatric patients aged 3 months and older. Use of Atropine Sulfate Ophthalmic Solution 1% is supported by evidence from adequate and well-controlled trials with additional safety data from published literature.

Due to the potential for systemic absorption, the use of atropine sulfate ophthalmic solution, 1% in pediatric patients aged 3 months to 3 years should be

limited to no more than one drop per eye per day.

Use in pediatric patients younger than 3 months of age is not recommended.

### 8.5 Geriatric Use

No overall differences in safety and effectiveness have been observed between elderly and younger adult patients.

## 10. OVERDOSAGE

In the event of accidental ingestion or toxic overdosage with atropine sulfate ophthalmic solution, supportive care may include a short acting barbiturate or diazepam 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.

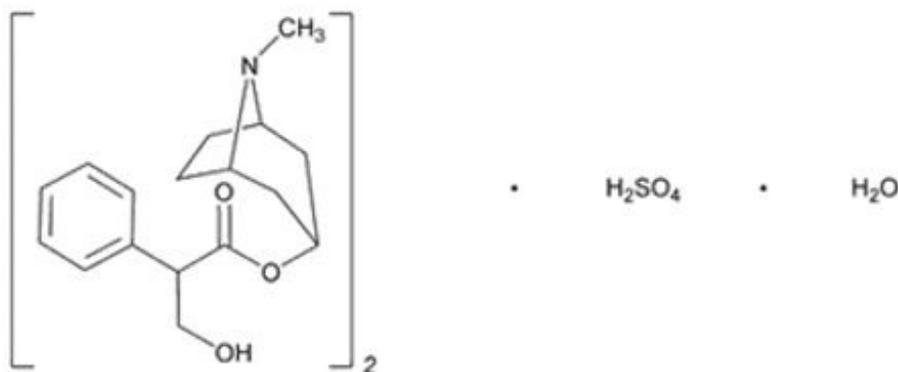
Physostigmine, given by slow intravenous injection of 1 to 4 mg (0.5 to 1 mg in pediatric populations), rapidly abolishes delirium and coma caused by large doses of atropine. Since physostigmine is rapidly destroyed, the patient may again lapse into coma after one to two hours, and repeated doses may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

Artificial respiration with oxygen may be necessary. Cooling measures may be needed to help to reduce fever, especially in pediatric populations.

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

## 11. DESCRIPTION

Atropine sulfate ophthalmic solution, 1% contains atropine an anticholinergic, in a sterile colorless, clear solution for topical ophthalmic use. The active ingredient is represented by the chemical structure



**Chemical Name:** Benzeneacetic acid,  $\alpha$ -(hydroxymethyl)-, 8-methyl-8-azabicyclo[3.2.1]oct-3-yl ester, endo-(±)-, sulfate (2:1) (salt), monohydrate.

**Molecular Formula:**  $(C_{17}H_{23}NO_3)_2 \cdot H_2SO_4 \cdot H_2O$

**Molecular Weight:**694.84 g/mol

Atropine sulfate appears as white or almost white, crystalline powder, or colorless crystals. It is very soluble in water and freely soluble in ethanol (96%).

Atropine sulfate ophthalmic solution, USP 1% is a clear, colorless, slightly viscous solution.

Each mL of Atropine Sulfate Ophthalmic Solution, USP 1% contains:

**Active:** atropine sulfate 10 mg (equivalent to 8.3 mg of atropine).

**Inactives:**benzalkonium chloride 0.1 mg (0.01%), edetate disodium dihydrate, hypromellose (methocel E4M premium), sodium phosphate dibasic heptahydrate, sodium phosphate monobasic monohydrate, hydrochloric acid and/or sodium hydroxide may be added to adjust pH (3.5 to 6.0), and water for injection USP.

## 12. CLINICAL PHARMACOLOGY

### 12.1 Mechanism of Action

Atropine is a reversible antagonist of muscarine-like actions of acetyl-choline and is therefore classified as an antimuscarinic agent. Atropine is relatively selective for muscarinic receptors. Its potency at nicotinic receptors is much lower, and actions at non-muscarinic receptors are generally undetectable clinically. Atropine does not distinguish among the M1, M2, and M3 subgroups of muscarinic receptors.

The pupillary constrictor muscle depends on muscarinic cholinceptor activation. This activation is blocked by topical atropine resulting in unopposed sympathetic dilator activity and mydriasis. Atropine also weakens the contraction of the ciliary muscle, or cycloplegia. Cycloplegia results in loss of the ability to accommodate such that the eye cannot focus for near vision.

### 12.2 Pharmacodynamics

The onset of action after administration of atropine sulfate ophthalmic solution 1%, is usually within 40 minutes with maximal effect being reached in about 2 hours. The effect can last for up to 2 weeks in a normal eye.

### 12.3 Pharmacokinetics

The bioavailability of atropine sulfate ophthalmic solution, 1% was assessed in six healthy subjects, 24 to 29 years of age. Subjects received either 0.3 mg atropine sulfate administered as bolus intravenous injection or 0.3 mg administered as 30 mcL instilled unilaterally in the cul-de-sac of the eye. Plasma l-hyoscyamine concentrations were determined over selected intervals up to eight hours after dose administration.

The mean bioavailability of topically applied atropine was  $63.5 \pm 29\%$  (range 19 to 95%) with large inter-individual differences. Mean maximum observed plasma concentration for the ophthalmic solution was  $288 \pm 73$  pg/mL. Maximum concentration was reached in  $28 \pm 27$  min after administration. Terminal half-life of l-hyoscamine was not affected by route of administration and was calculated to be  $3 \pm 1.2$  hours (intravenous) and  $2.5 \pm 0.8$  hours (topical ophthalmic).

In another placebo-controlled study, the systemic exposure to l-hyoscyamine, and the anti-cholinergic effects of atropine were investigated in eight ocular surgery patients 56 to 66 years of age, following single topical ocular 0.4 mg atropine dose (given as 40 microliters of atropine sulfate ophthalmic solution, 1%). The mean ( $\pm$  standard deviation (SD))  $C_{max}$  of l-hyoscyamine in these patients was  $860 \pm 402$  pg/mL, achieved within 8 minutes of eyedrop instillation.

Following intravenous administration, the mean ( $\pm$  SD) elimination half-life ( $t_{1/2}$ ) of atropine was reported to be longer in pediatric subjects under 2 years ( $6.9 \pm 3.3$  hours) and in geriatric patients 65 to 75 years ( $10 \pm 7.3$  hours), compared to in children over 2 years ( $2.5 \pm 1.2$  hours) and in adults 16 to 58 years ( $3 \pm 0.9$  hours) [see *Use in Specific Populations* ( 8.4)] .

Atropine is destroyed by enzymatic hydrolysis, particularly in the liver; from 13 to 50% is excreted unchanged in the urine. Traces are found in various secretions, including milk. The major metabolites of atropine are noratropine, atropin-n-oxide, tropine, and tropic acid. Atropine readily crosses the placental barrier and enters the fetal circulation but is not found in amniotic fluid.

Atropine binds poorly (about 44%) to plasma protein, mainly to alpha-1 acid glycoprotein; age has no effect on the serum protein binding of atropine. Atropine binding to  $\alpha$ -1 acid glycoprotein was concentration dependent (2 to 20 mcg/mL) and nonlinear *in vitro* and *in vivo*. There is no gender effect on the pharmacokinetics of atropine administered by injection.

## **13. NONCLINICAL TOXICOLOGY**

### **13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility**

#### Carcinogenesis

Long term studies in animals have not been performed to evaluate the carcinogenic potential of atropine sulfate.

#### Mutagenesis

Atropine sulfate was negative in the salmonella/microsome mutagenicity test.

#### Impairment of Fertility

Studies to evaluate impairment of fertility have not been conducted.

## **14. CLINICAL STUDIES**

Topical administration of atropine sulfate ophthalmic solution, 1% results in cycloplegia and mydriasis which has been demonstrated in several controlled clinical studies in adults and pediatric patients. Maximal mydriasis usually occurs in about 40 minutes and maximal cycloplegia is usually achieved in about 60 to 90 minutes after single administration. Full recovery usually occurs in approximately one week but may last a couple of weeks.

## **16. HOW SUPPLIED/STORAGE AND HANDLING**

Atropine sulfate ophthalmic solution, USP 1% is supplied in a plastic dropper bottle with a red cap in the following sizes:

NDC 60505-6226-0 2 mL bottle

NDC 60505-6226-1 5 mL bottle

NDC 60505-6226-2 15 mL bottle

- 
- 

**Storage:** Store at 20°C to 25°C (68°F to 77°F) [see USP Controlled Room Temperature]. Keep tightly closed. After opening, atropine sulfate ophthalmic solution can be used until the expiration date on the bottle.

## 17. PATIENT COUNSELING INFORMATION

### Risk of Contamination

Advise patients not to touch the dropper tip to the eye, eyelids, or any other surface as this may contaminate the solution. Keep the bottle tightly closed.

### Instillation Site Pain

Advise patients that drops will sting upon instillation.

### Sensitivity to Light and Blurred Vision

Advise patients that they will experience sensitivity to light and blurred vision which may last for a couple of weeks.

Manufactured By	Manufactured For
Apotex Inc.	Apotex Corp.
Toronto, Ontario	Weston, Florida
Canada M9L 1T9	USA 33326

Revised: September 2025

Rev. 4

Principal Display Panel Text for Container Label:

NDC 60505-6226-0

Atropine Sulfate

Ophthalmic

Solution, USP

1%

FOR TOPICAL

APPLICATION TO THE EYE

Sterile

Rx only

2 mL

2 mL NDC 60505-6226-0

**Atropine Sulfate**  
Ophthalmic Solution, USP

1%

FOR TOPICAL APPLICATION  
TO THE EYE  
Rx Only Sterile  
APOTEX CORP.

Each mL contains: **Active:** Atropine Sulfate 10 mg (1%), the amount of atropine in 10 mg of atropine sulfate is 8.3 mg. **Preservative:** Benzalkonium Chloride 0.1 mg (0.01%). **Storage:** Store at 20°C to 25°C (68°F to 77°F). Keep tightly closed. **WARNING - KEEP OUT OF THE REACH OF CHILDREN.**

Manufactured by: Apotex Inc. Toronto, Ontario Canada M9L 1T9  
Manufactured for: Apotex Corp. Weston, Florida 33326

413838

Principal Display Panel Text for Container Label:

NDC 60505-6226-1

Atropine Sulfate

Ophthalmic

Solution, USP

1%

FOR TOPICAL

APPLICATION TO THE EYE

Sterile

Rx only

5 mL

5 mL NDC 60505-6226-1

**Atropine Sulfate**  
Ophthalmic Solution, USP

1%

FOR TOPICAL APPLICATION  
TO THE EYE  
Rx Only Sterile  
APOTEX CORP.

Each mL contains: **Active:** Atropine Sulfate 10 mg (1%), the amount of atropine in 10 mg of atropine sulfate is 8.3 mg. **Preservative:** Benzalkonium Chloride 0.1 mg (0.01%). **Storage:** Store at 20°C to 25°C (68°F to 77°F). Keep tightly closed. **WARNING - KEEP OUT OF THE REACH OF CHILDREN.**

Manufactured by: Apotex Inc. Toronto, Ontario Canada M9L 1T9  
Manufactured for: Apotex Corp. Weston, Florida 33326

413836

Principal Display Panel Text for Container Label:

NDC 60505-6226-2

Atropine Sulfate

Ophthalmic

Solution, USP

1%

FOR TOPICAL

APPLICATION TO THE EYE

Sterile

Rx only

15 mL

15 mL      NDC 60505-6226-2

**Atropine Sulfate**  
Ophthalmic Solution, USP

1%

FOR TOPICAL APPLICATION  
TO THE EYE

Rx Only      Sterile

**APOTEX CORP.**

Each mL contains:  
**Active:** Atropine Sulfate 10 mg (1%), the amount of atropine in 10 mg of atropine sulfate is 8.3 mg. **Preservative:** Benzalkonium Chloride 0.1 mg (0.01%).  
**Storage:** Store at 20°C to 25°C (68°F to 77°F). Keep tightly closed.  
**WARNING – KEEP OUT OF THE REACH OF CHILDREN.**

Manufactured by: Apotex Inc. Toronto, Ontario Canada M9L 1T9  
Manufactured for: Apotex Corp. Weston, Florida 33326      413840

Principal Display Panel Text for Carton Label:

60505-6226-0

Atropine

Sulfate

Ophthalmic

Solution, USP

1%

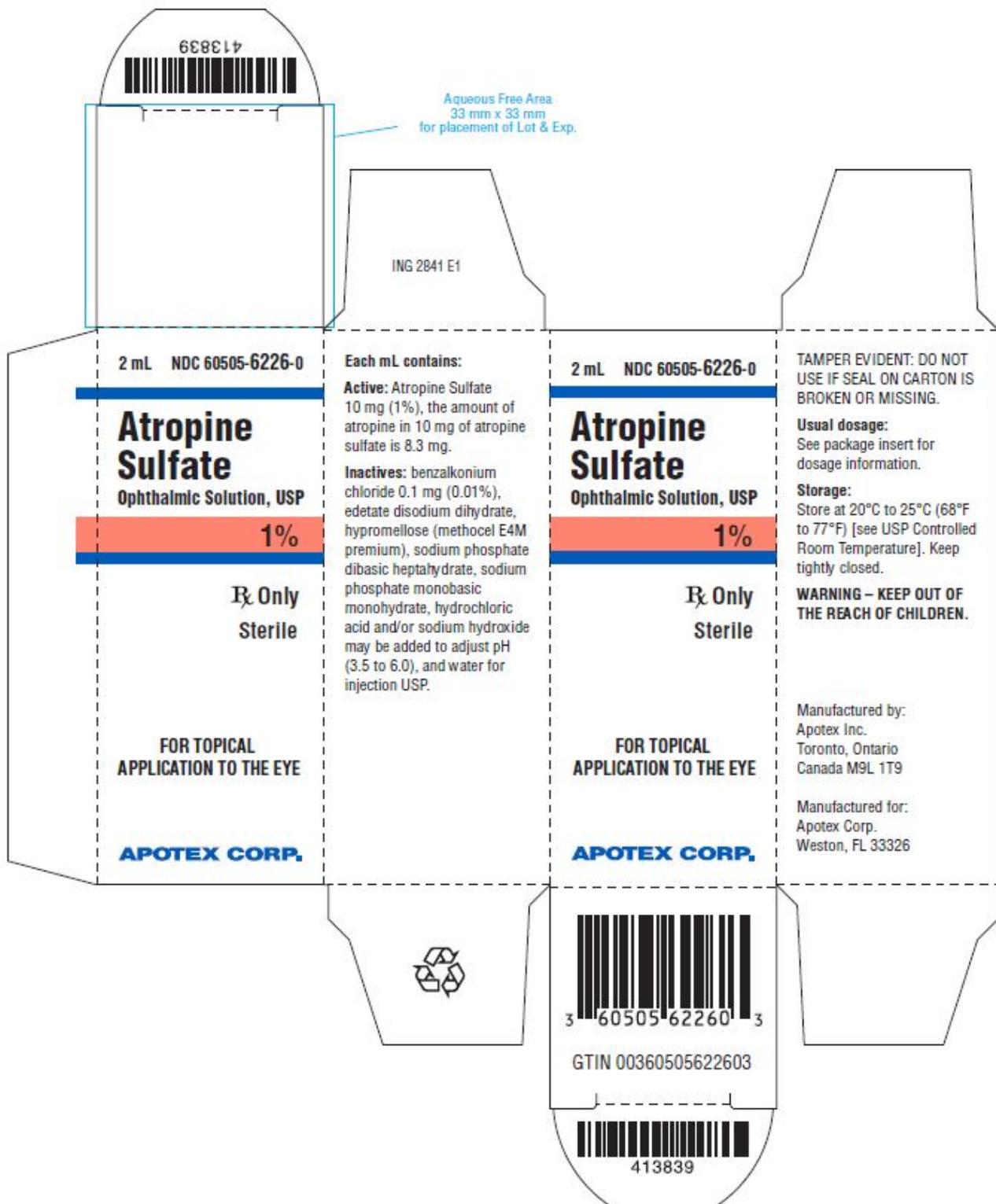
FOR TOPICAL APPLICATION

TO THE EYE

Sterile

2 mL

Rx only



Principal Display Panel Text for Carton Label:

60505-6226-1

Atropine

Sulfate

Ophthalmic

Solution, USP

1%

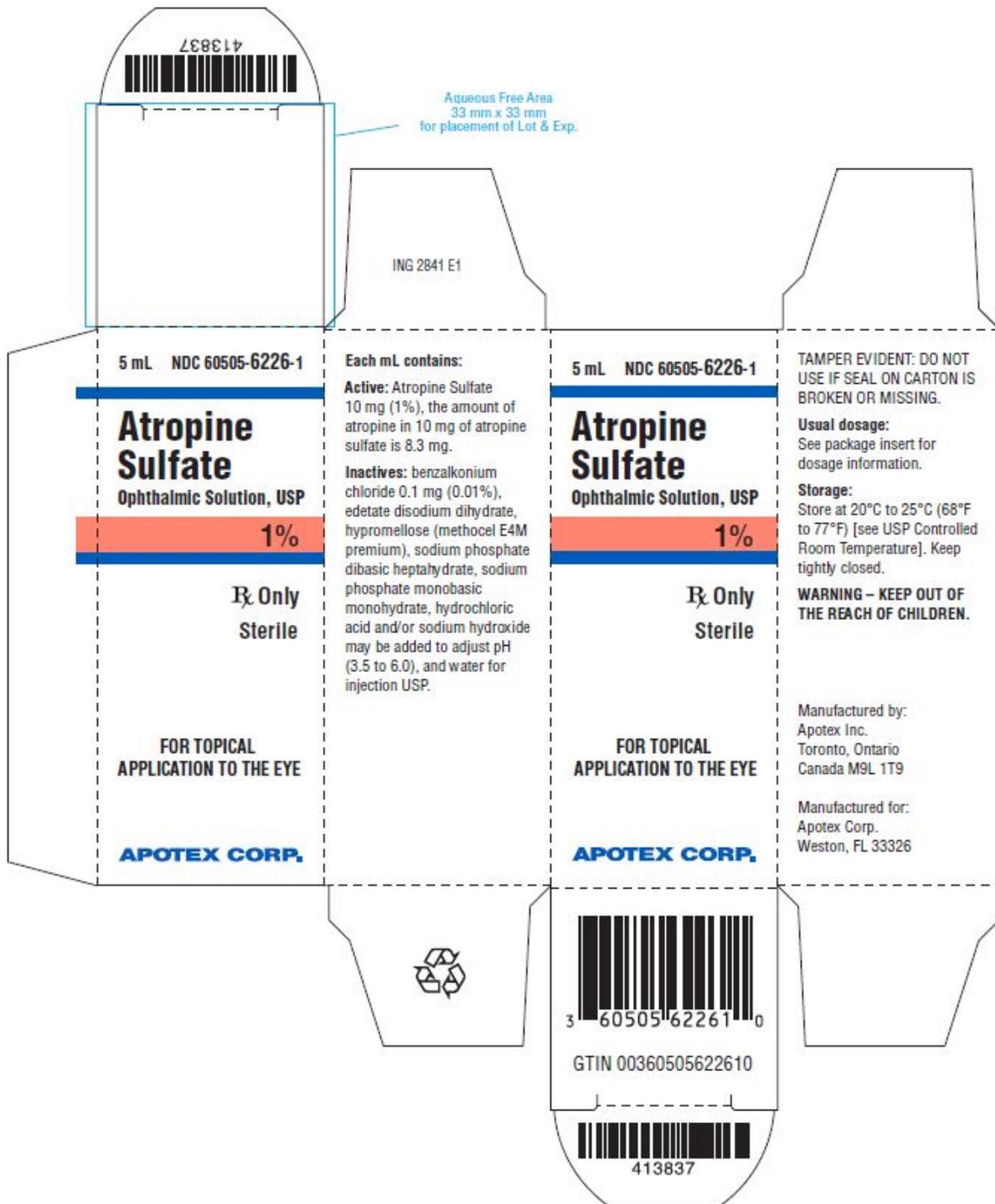
FOR TOPICAL APPLICATION

TO THE EYE

Sterile

5 mL

Rx only



Principal Display Panel Text for Carton Label:

60505-6226-2

Atropine

Sulfate

Ophthalmic

Solution, USP

1%

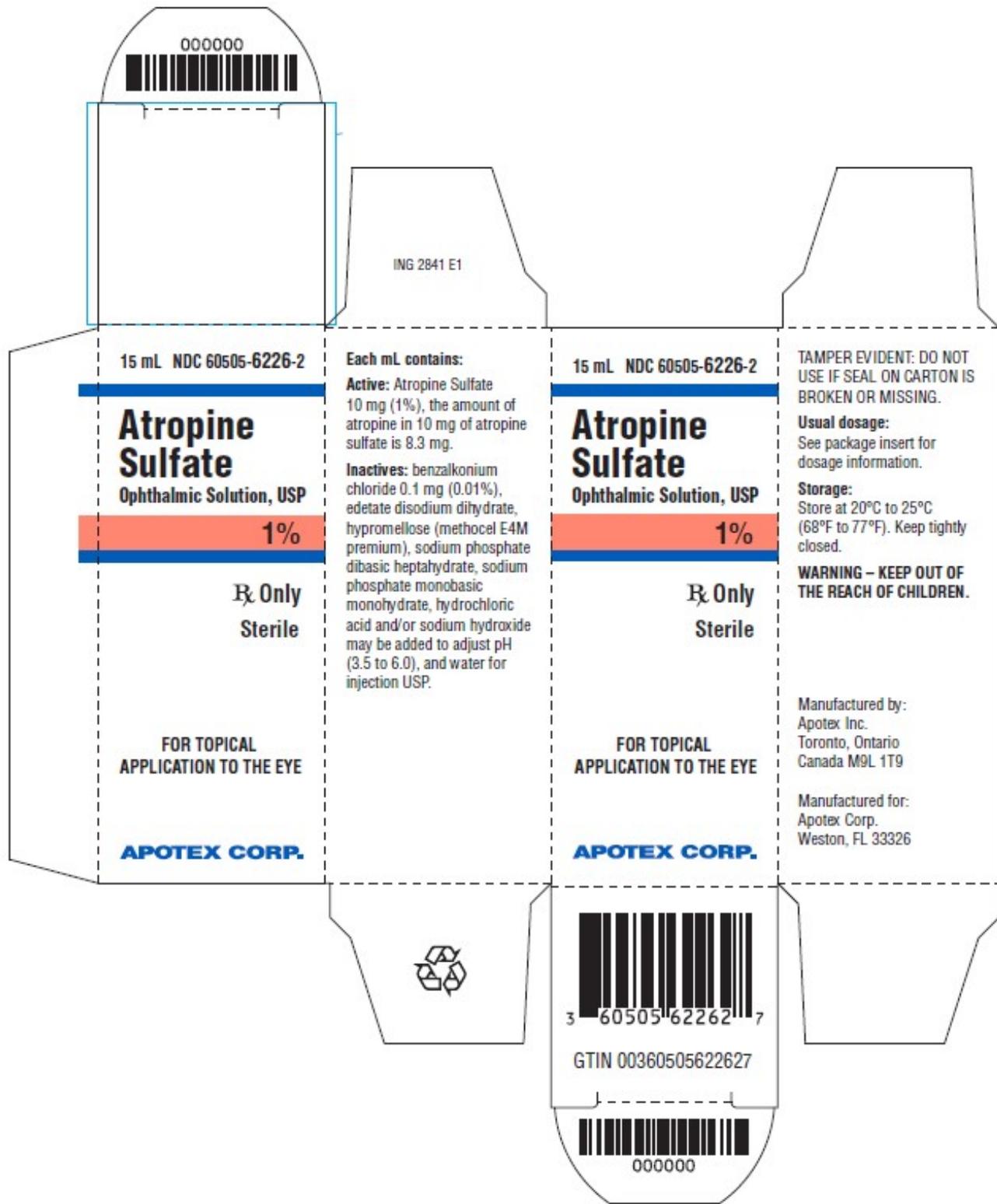
FOR TOPICAL APPLICATION

TO THE EYE

Sterile

15 mL

Rx only



## ATROPINE

atropine sulfate solution/ drops

### Product Information

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:67296-2200(NDC:60505-6226)
<b>Route of Administration</b>	OPHTHALMIC		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<b>ATROPINE SULFATE</b> (UNII: 03J5ZE7KA5) (ATROPINE - UNII:7C0697DR9I)	ATROPINE SULFATE	10 mg in 1 mL

**Inactive Ingredients**

Ingredient Name	Strength
<b>BENZALKONIUM CHLORIDE</b> (UNII: F5UM2KM3W7)	
<b>SODIUM PHOSPHATE, DIBASIC, UNSPECIFIED FORM</b> (UNII: GR686LBA74)	
<b>EDETATE DISODIUM</b> (UNII: 7FLD91C86K)	
<b>HYPROMELLOSE 2910 (4000 MPA.S)</b> (UNII: RN3152OP35)	
<b>SODIUM PHOSPHATE, MONOBASIC, UNSPECIFIED FORM</b> (UNII: 3980JIH2SW)	
<b>HYDROCHLORIC ACID</b> (UNII: QTT17582CB)	
<b>SODIUM HYDROXIDE</b> (UNII: 55X04QC32I)	
<b>WATER</b> (UNII: 059QF0KO0R)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67296-2200-5	1 in 1 CARTON	11/26/2021	
1		5 mL in 1 BOTTLE, DROPPER; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA215624	11/26/2021	

**Labeler** - Redpharm Drug (828374897)**Establishment**

Name	Address	ID/FEI	Business Operations
Redpharm Drug		828374897	repack(67296-2200)

Revised: 12/2025

Redpharm Drug