

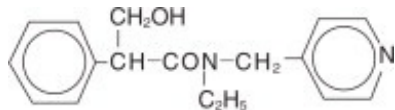
TROPICAMIDE- tropicamide solution/ drops
Akorn, Inc.

Tropicamide Ophthalmic Solution, USP

Rx only

DESCRIPTION:

Tropicamide Ophthalmic Solution, USP is an anticholinergic prepared as a sterile topical ophthalmic solution in two strengths. The active ingredient is represented by the structural formula:



C₁₇H₂₀N₂O₂ MW=284.36

Established name: Tropicamide

Chemical name: Benzeneacetamide, *N*-ethyl- α -(hydroxymethyl)-*N*-(4-pyridinylmethyl)-.

Each mL contains: Active: Tropicamide 0.5% (5 mg) or 1% (10 mg). **Inactives:** Edetate Disodium, Sodium Chloride, Hydrochloric Acid and/or Sodium Hydroxide (to adjust pH), Water for Injection. pH range 4.0 to 5.8. **Preservative:** Benzalkonium Chloride 0.01%.

CLINICAL PHARMACOLOGY:

This anticholinergic preparation blocks the responses of the sphincter muscle of the iris and the ciliary muscle to cholinergic stimulation, dilating the pupil (mydriasis). The stronger preparation (1%) also paralyzes accommodation. This preparation acts in 15-30 minutes and the duration of activity is approximately 3-8 hours. Complete recovery from mydriasis in some individuals may require 24 hours. The weaker strength may be useful in producing mydriasis with only slight cycloplegia. Heavily pigmented irides may require more doses than lightly pigmented irides.

INDICATIONS AND USAGE:

For mydriasis and cycloplegia for diagnostic procedures.

CONTRAINDICATIONS:

Contraindicated in persons showing hypersensitivity to any component of this preparation.

WARNINGS:

For topical use only — not for injection.

This preparation may cause CNS disturbances which may be dangerous in pediatric patients. The possibility of psychotic reactions and behavioral disturbances due to hypersensitivity to anticholinergic drugs should be considered.

Mydriatics may produce a transient elevation of intraocular pressure.

Remove contact lenses before using.

PRECAUTIONS:

General: The lacrimal sac should be compressed by digital pressure for two to three minutes after instillation to avoid excessive systemic absorption.

Information for Patients: Do not touch dropper tip to any surface, as this may contaminate the solution. Patient should be advised not to drive or engage in potentially hazardous activities while pupils are dilated. Patient 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 child's mouth and to wash their own hands and the child's hands following administration.

Drug Interactions: Tropicamide may interfere with the antihypertensive action of carbachol, pilocarpine, or ophthalmic cholinesterase inhibitors.

Carcinogenesis, Mutagenesis, Impairment of Fertility: There have been no long-term studies done using tropicamide in animals to evaluate carcinogenic potential.

Pregnancy: Pregnancy Category C. Animal reproduction studies have not been conducted with tropicamide. It is also not known whether tropicamide can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Tropicamide should be given to a pregnant woman only if clearly needed.

Nursing Mothers: It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when tropicamide is administered to a nursing woman.

Pediatric Use: Tropicamide may rarely cause CNS disturbances which may be dangerous in pediatric patients. Psychotic reactions, behavioral disturbances, and vasomotor or cardiorespiratory collapse in children have been reported with the use of anticholinergic drugs (See WARNINGS). Keep this and all medications out of the reach of children.

ADVERSE REACTIONS:

Ocular: Transient stinging, blurred vision, photophobia and superficial punctate keratitis have been reported with the use of tropicamide. Increased intraocular pressure has been reported following the use of mydriatics.

Non-Ocular: Dryness of the mouth, tachycardia, headache, allergic reactions, nausea, vomiting, pallor, central nervous system disturbances and muscle rigidity have been reported with the use of tropicamide. Psychotic reactions, behavioral disturbances, and vasomotor or cardiorespiratory collapse in children have been reported with the use of anticholinergic drugs.

DOSAGE AND ADMINISTRATION:

For refraction, instill one or two drops of 1% solution in the eye(s), repeated in five minutes. If patient is not seen within 20 to 30 minutes, an additional drop may be instilled to prolong mydriatic effect. For examination of fundus, instill one or two drops of 0.5% solution 15 to 20 minutes prior to examination. Individuals with heavily pigmented irides may require higher strength or more doses. Mydriasis will reverse spontaneously with time, typically in 4 to 8 hours. However, in some cases, complete recovery may take up to 24 hours.

HOW SUPPLIED:

Tropicamide Ophthalmic Solution USP, 0.5% and 1% are supplied as sterile solutions in plastic dropper bottles.

0.5% NDC 17478-101-12 (15 mL)

1% NDC 17478-102-12 (15 mL)

1% NDC 17478-102-20 (2 mL)

STORAGE: Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature]. Do not refrigerate or store at high temperatures. Keep container tightly closed.

Akorn

Manufactured by: **Akorn, Inc.**

Lake Forest, IL 60045

TC00N Rev. 10/16

Principal Display Panel Text for Container Label:

NDC 17478-101-12

Tropicamide

Ophthalmic

Solution, USP

0.5%

Sterile

15 mL

Rx only

For Topical Ophthalmic Use Only

The image shows a rectangular label with rounded corners and a red border. On the left side, there are two vertical columns: 'EXP.' and 'LOT'. Below these is a barcode with the number '(01)00317478101123' printed vertically to its left. The main body of the label contains the following text:

Each mL contains:
Active: Tropicamide 0.5% (5 mg); **Inactives:** Edetate Disodium, Sodium Chloride, Hydrochloric Acid and/or Sodium Hydroxide may be added to adjust pH (4.0 to 5.8) and Water for Injection;
Preservative: Benzalkonium Chloride 0.01%.
PRECAUTION: Do not touch dropper tip to any surface, as this may contaminate the solution.

NDC 17478-101-12

**Tropicamide
Ophthalmic
Solution, USP**

0.5%

**Sterile
15 mL**

Rx only

FOR TOPICAL OPHTHALMIC USE ONLY

A Sterile Anticholinergic Agent.
Usual Dosage: One or two drops topically in the eye(s). See package insert for dosage information.
Storage: Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature]. Do not refrigerate or store at high temperatures. Keep tightly closed.
Mfd. by: **Akorn, Inc.**
Lake Forest, IL 60045
TCAHL Rev. 10/16

Principal Display Panel Text for Carton Label:

NDC 17478-101-12

Tropicamide

Ophthalmic

Solution, USP

0.5%

For Topical Ophthalmic

Use only.

Sterile

15 mL

Rx only [Akorn logo]



Principal Display Panel Text for Container Label:

NDC 17478-102-12

Tropicamide

Ophthalmic

Solution, USP

1%

Sterile

15 mL

Rx only

For Topical Ophthalmic Use Only

The image shows a rectangular label with rounded corners and a red border. On the left side, there are two columns: 'EXP.' and 'LOT', each with a corresponding empty box. Below these is a barcode with the number '(01)00317478102120' printed vertically to its left. The main text of the label is organized into several sections. At the top left, it says 'Each mL contains:'. Below this, it lists the active ingredient 'Tropicamide 1% (10 mg)' and inactive ingredients: 'Edetate Disodium, Sodium Chloride, Hydrochloric Acid and/or Sodium Hydroxide may be added to adjust pH (4.0 to 5.8) and Water for Injection;'. It also lists the preservative: 'Benzalkonium Chloride 0.01%'. A 'PRECAUTION' section follows, stating 'Do not touch dropper tip to any surface, as this may contaminate the solution.'. In the center, the NDC number 'NDC 17478-102-12' is printed above the product name 'Tropicamide Ophthalmic Solution, USP'. Below the product name is a red horizontal bar containing the text '1%'. Underneath the bar, it says 'Sterile 15 mL' and 'Rx only'. At the bottom center, it reads 'FOR TOPICAL OPHTHALMIC USE ONLY'. On the right side of the label, there is a paragraph describing the product as 'A Sterile Anticholinergic Agent'. Below this, it provides 'Usual Dosage' information: 'One or two drops topically in the eye(s). See package insert for dosage information.'. It also includes 'Storage' instructions: 'Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature]. Do not refrigerate or store at high temperatures. Keep tightly closed.'. At the bottom right, it lists the manufacturer: 'Mfd. by: Akorn, Inc. Lake Forest, IL 60045' and the revision date: 'TCBHL Rev. 10/16'.

EXP. LOT

(01)00317478102120

Each mL contains:
Active: Tropicamide 1% (10 mg); **Inactives:** Edetate Disodium, Sodium Chloride, Hydrochloric Acid and/or Sodium Hydroxide may be added to adjust pH (4.0 to 5.8) and Water for Injection;
Preservative: Benzalkonium Chloride 0.01%.
PRECAUTION: Do not touch dropper tip to any surface, as this may contaminate the solution.

NDC 17478-102-12

**Tropicamide
Ophthalmic
Solution, USP**

1%

**Sterile
15 mL**

Rx only

FOR TOPICAL OPHTHALMIC USE ONLY

A Sterile Anticholinergic Agent.
Usual Dosage: One or two drops topically in the eye(s). See package insert for dosage information.
Storage: Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature]. Do not refrigerate or store at high temperatures. Keep tightly closed.
Mfd. by: **Akorn, Inc.**
Lake Forest, IL 60045
TCBHL Rev. 10/16

Principal Display Panel Text for Carton Label:

NDC 17478-102-12

Tropicamide

Ophthalmic

Solution, USP

1%

For Topical Ophthalmic

Use only.

Sterile

15 mL

Rx only [Akorn logo]



TCBHC 1016

NDC 17478-102-12

NDC 17478-102-12

A Sterile Anticholinergic Agent.
Usual Dosage: One or two drops topically in the eye(s). See package insert for dosage information.

Storage: Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature]. Do not refrigerate or store at high temperatures. Keep container tightly closed.

Tropicamide Ophthalmic Solution, USP

1%

FOR TOPICAL OPHTHALMIC USE ONLY.

Each mL contains:

Active: Tropicamide 1% (10 mg);
Inactives: Edetate Disodium, Sodium Chloride, Hydrochloric Acid and/or Sodium Hydroxide may be added to adjust pH (4.0 to 5.8) and Water for Injection;
Preservative: Benzalkonium Chloride 0.01%.

Tropicamide Ophthalmic Solution, USP

1%

FOR TOPICAL OPHTHALMIC USE ONLY.

PRECAUTION: Do not touch dropper tip to any surface, as this may contaminate the solution.

WARNING - KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN.

DO NOT USE IF IMPRINTED SEAL IS BROKEN OR MISSING.

Sterile

15 mL

Rx only AKORN



Manufactured by:
Akorn, Inc.
Lake Forest, IL 60045
TCBHC Rev. 10/16

Sterile

15 mL

Rx only AKORN

TROPICAMIDE

tropicamide solution/ drops

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:17478-102
Route of Administration	OPHTHALMIC		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Tropicamide (UNII: N0A3Z5XTC6) (Tropicamide - UNII:N0A3Z5XTC6)	Tropicamide	10 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
benzalkonium chloride (UNII: F5UM2KM3W7)	
edetate disodium (UNII: 7FLD91C86K)	
sodium chloride (UNII: 451W471Q8X)	
sodium hydroxide (UNII: 55X04QC32I)	
hydrochloric acid (UNII: QTT17582CB)	
water (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:17478-102-12	1 in 1 CARTON	09/29/2000	
1		15 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product		
2	NDC:17478-102-20	1 in 1 CARTON	09/29/2000	
2		2 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA040315	09/29/2000	

TROPICAMIDE

tropicamide solution/ drops

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:17478-101
Route of Administration	OPHTHALMIC		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Tropicamide (UNII: N0A3Z5XTC6) (Tropicamide - UNII:N0A3Z5XTC6)	Tropicamide	5 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
benzalkonium chloride (UNII: F5UM2KM3W7)	
edetate disodium (UNII: 7FLD91C86K)	
sodium chloride (UNII: 451W47IQ8X)	
sodium hydroxide (UNII: 55X04QC32I)	
hydrochloric acid (UNII: QTT17582CB)	
water (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:17478-101-12	1 in 1 CARTON	09/29/2000	
1		15 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA040314	09/29/2000	

Labeler - Akorn, Inc. (062649876)

Establishment

Name	Address	ID/FEI	Business Operations
Akorn, Inc.		155135783	MANUFACTURE(17478-102, 17478-101) , REPACK(17478-102, 17478-101) , ANALYSIS(17478-102, 17478-101)

Revised: 12/2017

Akorn, Inc.