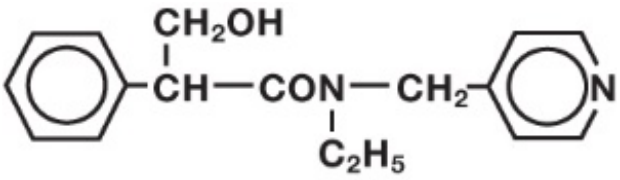
TROPICAMIDE- tropicamide solution/ drops
Sandoz Inc

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 chemical structure:



Established name: Tropicamide ophthalmic solution

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

Each mL contains: Active: tropicamide 1%. **Preservative:** benzalkonium chloride 0.01%. **Inactives:** sodium chloride, edetate disodium, hydrochloric acid and/or sodium hydroxide (to adjust pH), purified water. pH 4.0 - 5.8.

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 ophthalmic 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 reduce 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.

Geriatric Use: No overall differences in safety or effectiveness have been observed between elderly and younger patients.

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 cardio-respiratory 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 or 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.

To report SUSPECTED ADVERSE REACTIONS, contact Sandoz Inc. at 1-800-525-8747 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

HOW SUPPLIED

3mL and 15mL in plastic dispensers.

1% - 3 mL: **NDC** 61314-355-01

1% - 15 mL: **NDC** 61314-355-02

STORAGE: Store at 8° to 27°C (46° to 80°F). Do not refrigerate or store at high temperatures. Keep container tightly closed.

Revised: 11-2021

300051858-1121

SANDOZ
Manufactured by
Alcon Laboratories, Inc.
Fort Worth, Texas 76134 for
Sandoz Inc.
Princeton, NJ 08540

PACKAGE/LABEL PRINCIPAL DISPLAY PANEL

NDC 61314-355-01
Tropicamide

Ophthalmic

Solution, USP

1%

Rx only

STERILE

3 mL

SANDOZ A Novartis Division

Side Panel:

A Sterile Anticholinergic Agent

Usual Dosage: One or two drops topically in the eye(s). Read enclosed insert.

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

Storage: Store at 8° to 27°C (46° to 80°F). Do not refrigerate or store at high temperature. Keep container tightly closed.

Ingredients: Each mL contains: Active: tropicamide 1%. **Preservative:** benzalkonium chloride 0.01%. **Inactives:** sodium chloride, edetate disodium, hydrochloric acid and/or sodium hydroxide (to adjust pH), purified water. pH 4.0 - 5.8.

Keep out of the reach of children.

Manufactured by Alcon Laboratories, Inc.

Fort Worth, Texas 76134 for Sandoz Inc., Princeton, NJ 08540

Product of Japan

9017187-0620

Rev. 06/2020

TROPICAMIDE

tropicamide solution/ drops

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:61314-355
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)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
HYDROCHLORIC ACID (UNII: QTT17582CB)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61314-355-01	1 in 1 CARTON	06/13/2000	
1		3 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
2	NDC:61314-355-02	1 in 1 CARTON	06/13/2000	
2		15 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA084306	06/13/2000	

Labeler - Sandoz Inc (005387188)

Registrant - Alcon Laboratories, Inc. (008018525)

Establishment

Name	Address	ID/FEI	Business Operations
Alcon Research, LLC		007672236	manufacture(61314-355)

Revised: 6/2022 Sandoz Inc