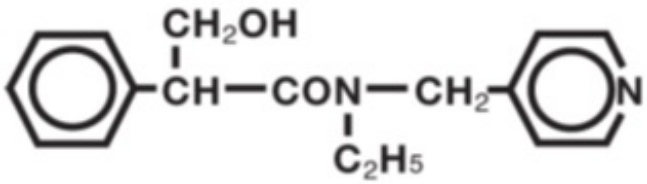
TROPICAMIDE - tropicamide solution/ drops
Somerset Therapeutics, LLC

Tropicamide Ophthalmic Solution, USP 1%
Somerset Therapeutics, LLC

DESCRIPTION

Tropicamide Ophthalmic Solution, USP is an anticholinergic prepared as a sterile topical ophthalmic solution. The active ingredient is represented by the chemical structure:



Established name:

Tropicamide ophthalmic solution, USP

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), Water for injection. pH range 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

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 punctuate 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. 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, 1% (15 mL) filled in 15 mL Natural LDPE Bottle and natural LDPE nozzles with red colored HDPE caps.

NDC 70069-**121**-01

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

Rx only

For Product Inquiry call 1-800-417-9175.

Issued: August, 2019

Manufactured for:

Somerset Therapeutics, LLC

Hollywood, FL 33024

Made in India

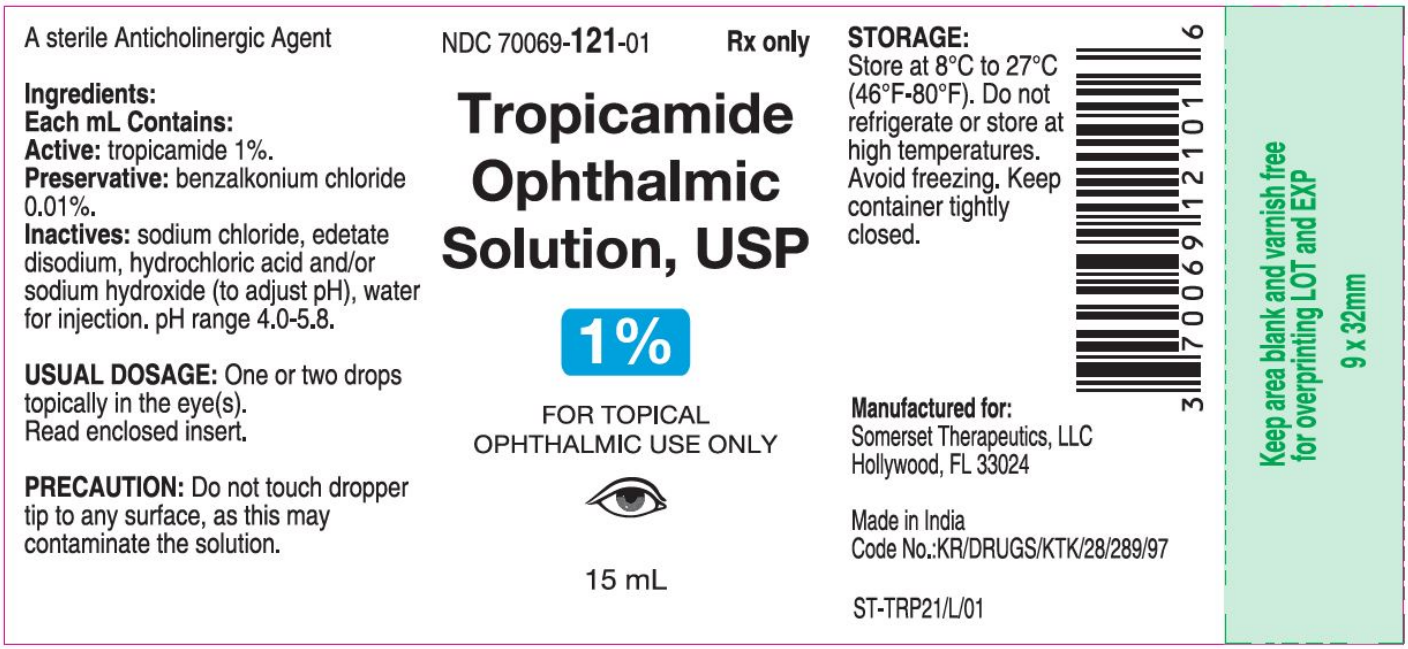
Code No.: KR/DRUGS/KTK/28/289/97

ST-TRP21/P/01

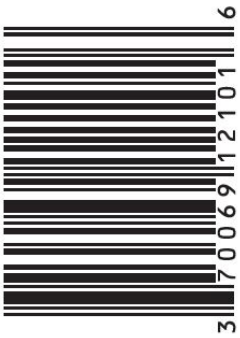
PSSO0484

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

Container Label



Carton Label



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ST-TRP21/C1/00

Rx only NDC 70069-**121**-01

Tropicamide Ophthalmic Solution, USP

1%

FOR TOPICAL
OPHTHALMIC USE ONLY

15 mL

Somerset Therapeutics LLC

A sterile Anticholinergic Agent

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), water for injection.
pH range 4.0 - 5.8.

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°C to 27°C (46°F-80°F). Do not refrigerate or store at high temperatures. Avoid freezing. Keep container tightly closed.

Rx only NDC 70069-**121**-01

Tropicamide Ophthalmic Solution, USP

1%

FOR TOPICAL
OPHTHALMIC USE ONLY

15 mL

Somerset Therapeutics LLC

TROPICAMIDE

tropicamide solution/ drops

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70069-121
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)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
HYDROCHLORIC ACID (UNII: QTT17582CB)	

WATER (UNII: 059QF0KO0R)	

Product Characteristics

Color	WHITE (Clear, colorless solution)	**Score**	
Shape		**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70069-121-01	1 in 1 CARTON	12/12/2019	
1		15 mL in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA207524	12/12/2019	

Labeler - Somerset Therapeutics, LLC (079947873)

Registrant - Somerset Therapeutics, LLC (079947873)

Establishment

Name	Address	ID/FEI	Business Operations
Somerset Therapeutics Limited		677236695	ANALYSIS(70069-121) , LABEL(70069-121) , MANUFACTURE(70069-121) , PACK(70069-121)

Revised: 4/2023 Somerset Therapeutics, LLC