

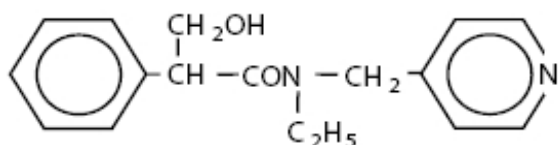
TROPICAMIDE- tropicamide solution/ drops
Bausch & Lomb Incorporated

**Tropicamide Ophthalmic
Solution, USP (Sterile)**

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 following chemical structure:



C₁₇H₂₀N₂O₂

Mol.wt. 284.36

Chemical name:

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

Each mL contains

ACTIVE: Tropicamide 5 mg (0.5%) or 10 mg (1%); INACTIVES: Boric Acid, Hydrochloric Acid, Edetate Disodium Dihydrate, Purified Water. Sodium Hydroxide and/or Hydrochloric Acid (to adjust pH) pH range 4.0 - 5.8. PRESERVATIVE ADDED: 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 (0.5%) 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 reaction and behavioral disturbance due to hypersensitivity to anticholinergic drugs should be considered.

Mydriatics may produce a transient elevation of intraocular pressure.

Remove contact lenses before using.

PRECAUTIONS

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.

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. Patients should be advised not to drive or engage in potentially 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 child's mouth and 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 cardiorespiratory collapse in children have been reported with the use of anticholinergic drugs.

To report SUSPECTED ADVERSE REACTIONS, contact Bausch + Lomb, a division of Valeant Pharmaceuticals North America LLC , at 1-800-321-4576 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

DOSAGE AND ADMINISTRATION

For refraction, one or two drops of the 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, one or two drops of the 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.

HOW SUPPLIED

Tropicamide Ophthalmic Solution, USP 1% is supplied in a plastic bottle with a red cap and a controlled drop tip in the following sizes:

2 mL - NDC 24208-585-59

15 mL - NDC 24208-585-64

Tropicamide Ophthalmic Solution, USP 0.5% is supplied in a plastic bottle with a red cap and a controlled drop tip in the following size:

15 mL - NDC 24208-590-64

Storage: Store at 20° to 25C (68° to 77°F); excursions permitted between 15° to 30°C (59° to 86°F) [See USP Controlled Room Temperature].

Keep container tightly closed.

DO NOT USE IF IMPRINTED "Protective Seal" WITH YELLOW  IS NOT INTACT.

KEEP OUT OF REACH OF CHILDREN.

Revised: July 2016

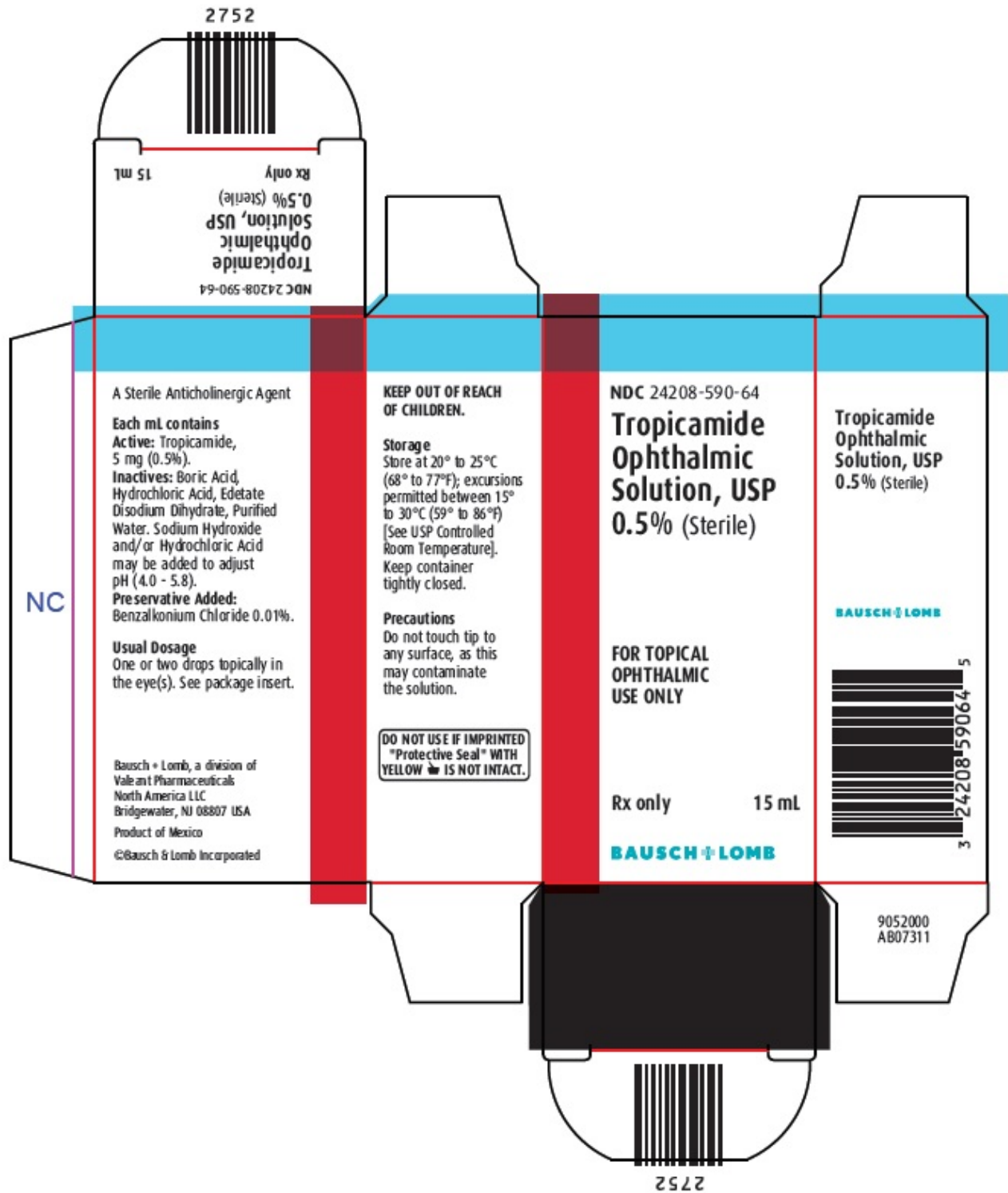
Bausch + Lomb, a division of
Valeant Pharmaceuticals North America LLC
Bridgewater, NJ 08807 USA

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9115805 (folded)

9115905 (flat)

PACKAGE/LABEL PRINCIPAL DISPLAY PANEL (Mexico) - 0.5



NDC 24208-590-64

**Tropicamide
Ophthalmic
Solution, USP**

0.5% (Sterile)

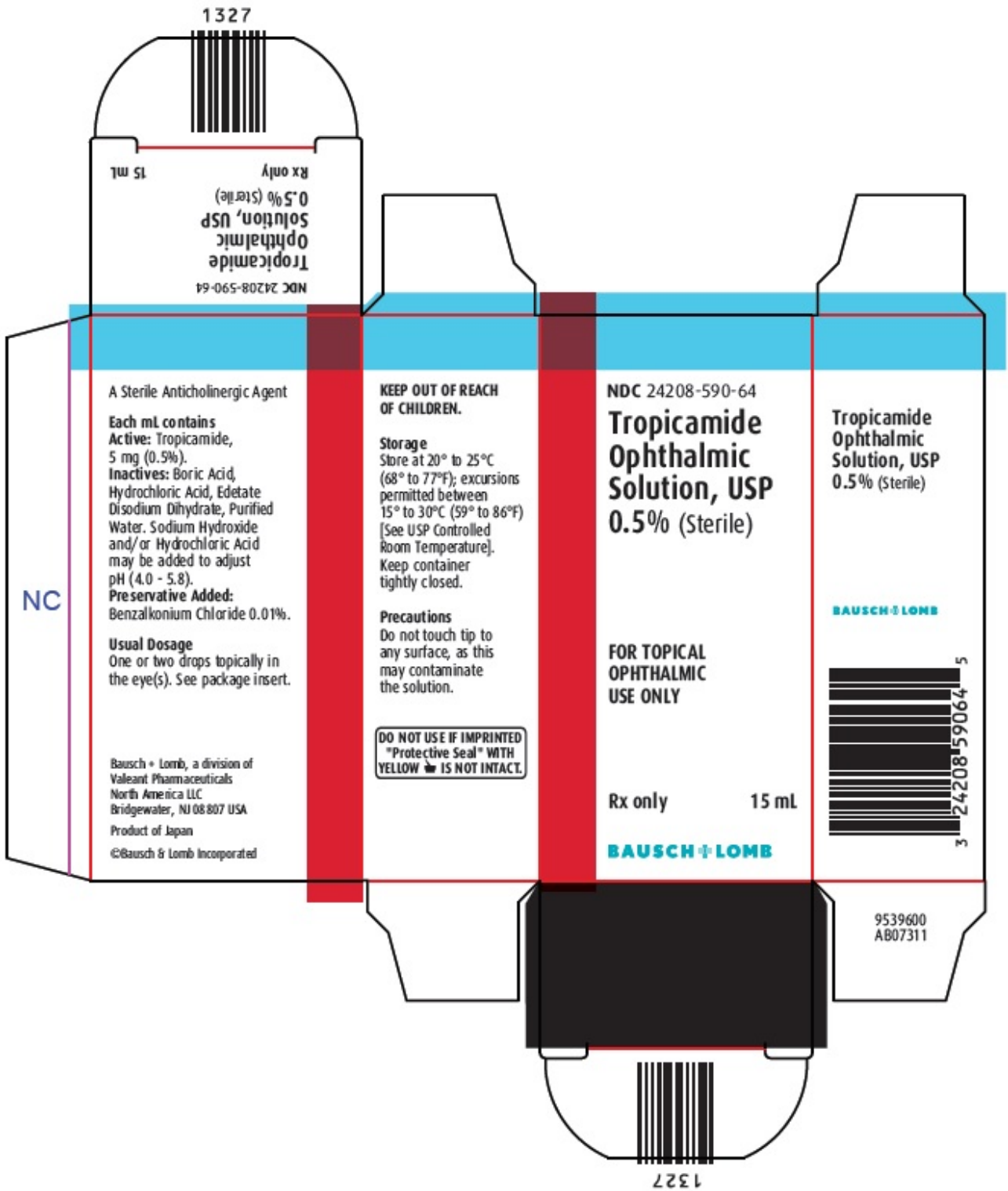
FOR TOPICAL
OPHTHALMIC
USE ONLY

Rx only

15 mL

BAUSCH + LOMB

PACKAGE/LABEL PRINCIPAL DISPLAY PANEL Japan – 0.5



NDC 24208-590-64

**Tropicamide
Ophthalmic
Solution, USP
0.5% (Sterile)**

**FOR TOPICAL
OPHTHALMIC
USE ONLY**

Rx only

15 mL

BAUSCH + LOMB

PACKAGE/LABEL PRINCIPAL DISPLAY PANEL Mexico 1

NDC 24208-585-64

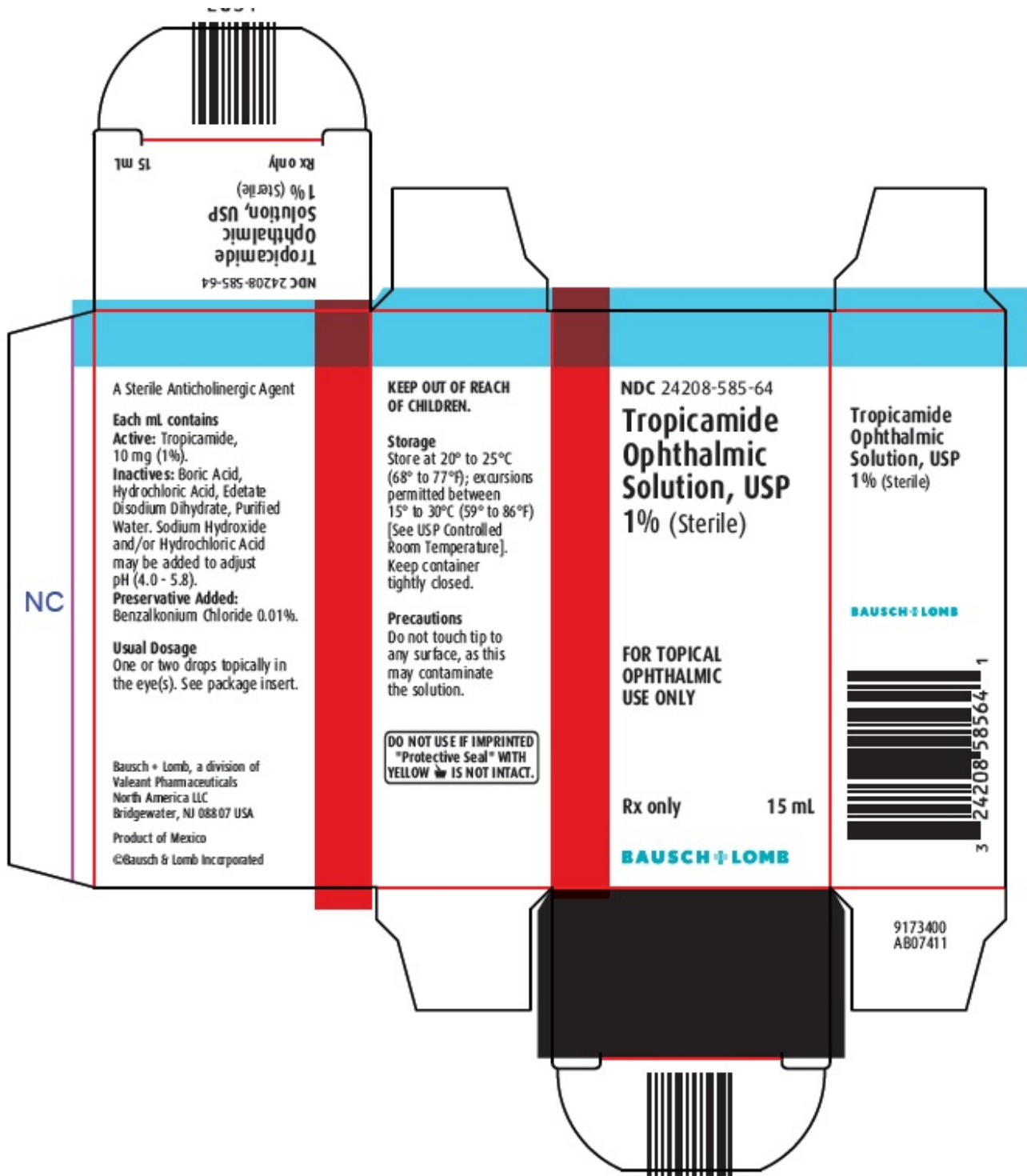
**Tropicamide
Ophthalmic
Solution, USP
1% (Sterile)**

FOR TOPICAL
OPHTHALMIC
USE ONLY

Rx only

15 mL

BAUSCH + LOMB



Package/Label Principal Display Panel Japan 1

NDC 24208-585-64

**Tropicamide
Ophthalmic
Solution, USP
1% (Sterile)**

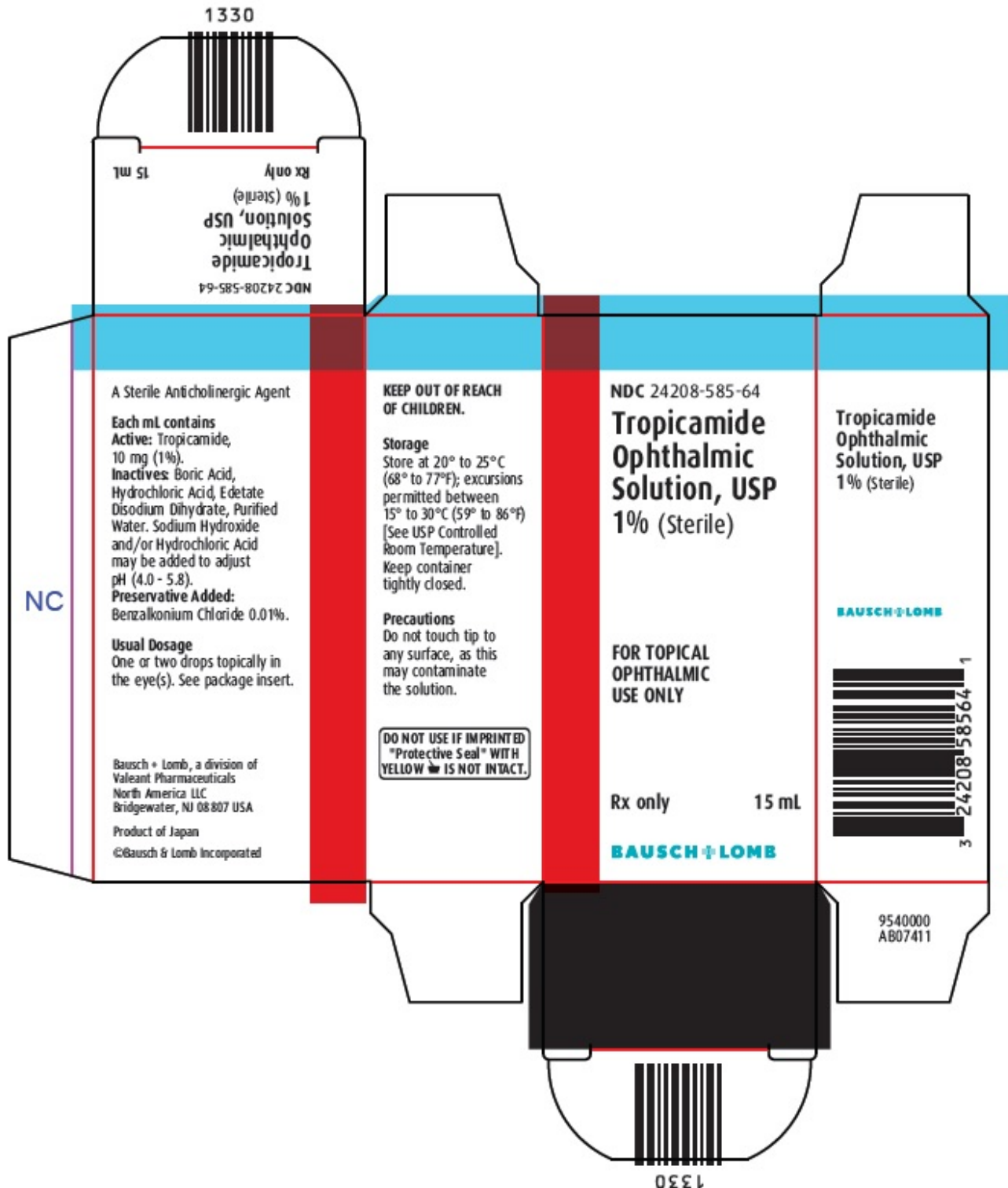
FOR TOPICAL

OPHTHALMIC
USE ONLY

Rx only

15 mL

BAUSCH + LOMB



TROPICAMIDE

tropicamide solution/ drops

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:24208-590
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)	
BORIC ACID (UNII: R57ZHV85D4)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
HYDROCHLORIC ACID (UNII: QTT17582CB)	
WATER (UNII: 059QF0KO0R)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:24208-590-64	1 in 1 CARTON	07/27/1994	
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	ANDA040067	07/27/1994	

TROPICAMIDE

tropicamide solution/ drops

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:24208-585
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)				
BORIC ACID (UNII: R57ZHV85D4)				
EDETATE DISODIUM (UNII: 7FLD91C86K)				
HYDROCHLORIC ACID (UNII: QTT17582CB)				
WATER (UNII: 059QF0KO0R)				
SODIUM HYDROXIDE (UNII: 55X04QC32I)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:24208-585-59	1 in 1 CARTON	07/27/1994	
1		2 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product		
2	NDC:24208-585-64	1 in 1 CARTON	07/27/1994	
2		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	ANDA040064	07/27/1994		

Labeler - Bausch & Lomb Incorporated (196603781)

Establishment

Name	Address	ID/FEI	Business Operations
Bausch & Lomb Incorporated		079587625	MANUFACTURE(24208-590, 24208-585)

Revised: 6/2016

Bausch & Lomb Incorporated