

SOOTHE XP PRESERVATIVE FREE- light mineral oil and mineral oil solution/ drops
Bausch & Lomb Incorporated

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Drug Facts

Active ingredients

Light mineral oil (1.0%)

Mineral oil (4.5%)

Purpose

Emollient

Emollient

Uses

- temporary relief of burning and irritation due to dryness of the eye
- temporary relief of discomfort due to minor irritations of the eye or to exposure to wind or sun
- as a protectant to prevent further irritation or to relieve dryness of the eye

Warnings

For external use only

Do not use

- if solution changes color
- if single-unit dispenser is not intact

When using this product

- do not touch the tip of container to any surface to avoid contamination
- once opened, discard
- do not reuse

Stop use and ask a doctor if

- you experience eye pain, changes in vision, continued redness or irritation of the eye, or if condition worsens or persists for more than 72 hours

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- remove contact lenses before use
- shake well before using
- to open, completely twist off tab
- instill 1 or 2 drop(s) in the affected eye(s) as needed or as directed by your doctor

Other information

- temporarily blurred vision is typical upon application
- drops appear as a milky white solution
- store at 15°-25°C (59°-77°F)

Inactive ingredients

boric acid, edetate disodium, octoxynol-40, polysorbate 80, purified water, sodium borate decahydrate. May contain hydrochloric acid and/or sodium hydroxide (to adjust pH).

Questions?

Call: 1-800-553-5340

Package/Label Principal Display Panel



NEW

BAUSCH + LOMB

Soothe® XP

Emollient (Lubricant) Eye Drops

Preservative Free

XTRA PROTECTION

Advanced Dry Eye Therapy

With Restoril® a unique combination of mineral oils that:

- Moisturizes for fast relief
- Protects against tear loss

- Restores the lipid layer of tears
- Gentle enough for sensitive eyes

- FL OZ EA (0.3 mL EA)

Sterile

30 Single-Use Dispensers

SOOTHE XP PRESERVATIVE FREE

light mineral oil and mineral oil solution/ drops

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:24208-742
Route of Administration	OPHTHALMIC		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LIGHT MINERAL OIL (UNII: N6K5787QVP) (LIGHT MINERAL OIL - UNII:N6K5787QVP)	LIGHT MINERAL OIL	10 mg in 1 mL
MINERAL OIL (UNII: T5L8T28FGP) (MINERAL OIL - UNII:T5L8T28FGP)	MINERAL OIL	45 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
BORIC ACID (UNII: R57ZHV85D4)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
OCTOXYNOL-40 (UNII: 9T1C662FKS)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
WATER (UNII: 059QF0KO0R)	
SODIUM BORATE (UNII: 91MBZ8H3QO)	
HYDROCHLORIC ACID (UNII: QTT17582CB)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:24208-742-01	30 in 1 CARTON	04/18/2018	
1		0.3 mL in 1 VIAL, SINGLE-USE; Type 0: Not a Combination Product		
2	NDC:24208-742-99	5 in 1 POUCH	08/22/2018	
2		0.3 mL in 1 VIAL, SINGLE-USE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part349	04/18/2018	

Labeler - Bausch & Lomb Incorporated (196603781)

Establishment

Name	Address	ID/FEI	Business Operations
Laboratoire Unither		574139809	MANUFACTURE(24208-742)

Establishment

Name	Address	ID/FEI	Business Operations
Calumet Karns City Refining LLC		114222776	API MANUFACTURE(24208-742)

Revised: 10/2019

Bausch & Lomb Incorporated