# SOOTHE XP- 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.

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#### **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

## When using this product

- do not touch the tip of container to any surface
- replace cap after using

## 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
- 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, polyquaternium-1 (preservative), polysorbate 80, purified water, sodium borate decahydrate. May contain hydrochloric acid and/or sodium hydroxide (to adjust pH).

#### **Questions?**

[phone icon] Call: 1-800-553-5340

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Order No. AB49311

SootheEyeDrops.com

Package/Label Principal Display Panel



**BAUSCH + LOMB** 

Soothe® XP

Emollient (Lubricant) Eye Drops

XTRA PROTECTION

## **Advanced Dry Eye Therapy**

# WITH RESTORYL® MINERAL OILS THAT:

- Restore
- Seal
- Protect

Sterile 0.5 FL OZ (15 mL)

AB49311 3839201

### **SOOTHE XP**

light mineral oil and mineral oil solution/ drops

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:24208-490
Route of Administration	OPHTHALMIC		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
<b>LIGHT MINERAL OIL</b> (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: 60ZP39ZG8H)			
WATER (UNII: 059QF0KO0R)			
SODIUM BORATE (UNII: 91MBZ8H3QO)			
HYDROCHLORIC ACID (UNII: QTT17582CB)			
SODIUM HYDROXIDE (UNII: 55X04QC32I)			

P	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:24208- 490-15	1 in 1 BOX	08/26/2010	
1		15 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product		

2	NDC:24208- 490-30	2 in 1 BOX	08/26/2010	
2		15 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product		
3	NDC:24208- 490-95	1 in 1 BOX	08/26/2010	
3		2.5 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
OTC monograph final	part349	08/26/2010	

## Labeler - Bausch & Lomb Incorporated (196603781)

Establishment				
Name	Address	ID/FEI	<b>Business Operations</b>	
Bausch & Lomb Incorporated		079587625	MANUFACTURE(24208-490)	

Revised: 9/2022 Bausch & Lomb Incorporated