# PURE EYES STERILE EYES- naphazoline hydrochloride and glycerin solution/drops

### SAMSON PHARMACEUTICAL

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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### Pure Eyes® Sterile Eyes

**DRUG FACT** 

ACTIVE INGREDIENTS	PURPOSE
Naphazoline HCL 0.01%	Redness reliever
Glycerin 0.25%	Lubricant

### Uses

- ♦ Relieve redness of the eye due to minor irritation
- ◆ Temporary relief of burning and irritation due to dryness of the eye
- ◆ Protects against further irritation

### Warnings

For external use only

Do not use if solution changes color or becomes cloudy

Ask a doctor before use if you have

### ♦ Narrow angle glaucoma

When using this product

- ♦ Do not touch tip of container to any surface to avoid contamination
- ♦ Do not overuse as it may products increased redness of the eye
- ◆ Pupils may be come enlarged temporarily
- Remove contact lenses before using
- ♦ Replace cap after use

Stop use and ask a doctor if

- You experience eye pain, changes in vision, continued redness or irritation of the eyes
- ♦ Conditions worsens or persists for more than 72 hours

Keep put of reach of children. Id swallowed, get medical help or contact a Poison Control Center right away.

### **Directions**

♦ Instill 1 to 2 drops in the affected eye(s) up to 4 times daily

### Other information

- ♦ Store at 15- 30 C (59-86 F)
- ♦ Keep tightly closed
- ♦ Use before expiration date marked on the carton and bottle
- ◆ Serious side effect associated with use of the product may be reported to the phone number provided below

### **Inactive ingredients**

benzalkonium chloride, boric acid, edetate disodium, purified water, sodium borate.

### **Question?**

1-888-995-9935

Manufactured by: Samson Pharmaceutical Commerce, CA 90040 Made in USA

### PRINCIPAL DISPLAY PANEL - 7 mL Bottle Blister Pack

**POCKET SIZE** 

### **MAXIMUM**

**REDNESS RELIEF** 

Pure Eyes®

### STERILE EYE DROPS

- ✓ Relieves
- ✓ Protects
- ✓ Soothes
- ✓ Moisturizes

Made in the **U.S.A.** 

0.24 FL OZ (7ML)





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# 10466004975

www.samsonpharmaceutical.com

Commerce, CA 90040

### **PURE EYES STERILE EYES**

naphazoline hydrochloride and glycerin solution/ drops

### **Product Information**

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:20146-7000

Route of Administration OPHTHALMIC

### **Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
Naphazoline Hydrochloride (UNII: MZ1131787D) (Naphazoline - UNII: H231GF11BV)	Naphazoline Hydrochloride	0.1 mg in 1 mL
Glycerin (UNII: PDC6A3C0OX) (Glycerin - UNII:PDC6A3C0OX)	Glycerin	2.5 mg in 1 mL

### **Inactive Ingredients**

Ingredient Name	Strength
benzalkonium chloride (UNII: F5UM2KM3W7)	
boric acid (UNII: R57ZHV85D4)	
edetate disodium (UNII: 7FLD91C86K)	
water (UNII: 059QF0KO0R)	
sodium borate (UNII: 91MBZ8H3QO)	

ı	Packaging			
	# Item Code	Package Description	Marketing Start Date	Marketing End Date
	<b>1</b> NDC:20146-7000-1	1 in 1 BLISTER PACK	01/01/2015	
	1	7 mL in 1 BOTTLE; Type 1: Convenience Kit of Co-Package		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part349	01/01/2015	

## Labeler - SAMSON PHARMACEUTICAL (088169581)

Establishment				
Name	Address	ID/FEI	Business Operations	
SAMSON PHARMACEUTICAL		088169581	MANUFACTURE(20146-7000)	

Revised: 1/2022 SAMSON PHARMACEUTICAL