NAPHAZOLINE HYDROCHLORIDE AND PHENIRAMINE MALEATE- naphazoline hydrochloride and pheniramine maleate solution/ drops
Akorn, Inc.

Drug Facts

Active ingredients

Naphazoline Hydrochloride 0.025%

Pheniramine Maleate 0.3%

Purpose

Redness reliever

Antihistamine

Uses

Temporarily relieves itchy, red eyes due to:

- pollen
- ragweed
- grass
- animal hair and dander

Warnings:

For external use only

Do not use if you are sensitive to any ingredient in this product

Ask a doctor before use if you have

- heart disease
- high blood pressure
- narrow angle glaucoma
- trouble urinating

When using this product

- pupils may become enlarged temporarily causing light sensitivity
- do not touch tip of container to any surface to avoid contamination
- replace cap after each use
- remove contact lenses before using
- do not use if this solution changes color or become cloudy
- overuse may cause more eye redness
- some users may experience a brief tingling sensation

Stop use and ask a doctor if

- you feel eye pain
- changes in vision occur
- redness or irritation of the eye lasts
- condition worsens or lasts more than 72 hours

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away. Accidental swallowing by infants and children may lead to coma and marked reduction in body temperature.

Directions

- adults and children 6 years of age and over: put 1 or 2 drops in the affected eye(s) up to four times a day
- children under 6 years of age: consult a doctor

Other information

- store between 20° to 25°C (68° to 77°F)

Inactive ingredients

Boric Acid and Sodium Borate buffer system preserved with Benzalkonium Chloride (0.01%) and Edetate Disodium (0.1%), Sodium Hydroxide and/or Hydrochloric Acid (to adjust pH) and Water for Injection.

Questions?

Call toll-free

1-800-932-5676

Principal Display Panel Text for Container Label:

NDC 17478-065-12

Naphazoline HCl 0.025%

and

Pheniramine Maleate 0.3%

Ophthalmic Solution, USP

ANTIHISTAMINE & REDNESS

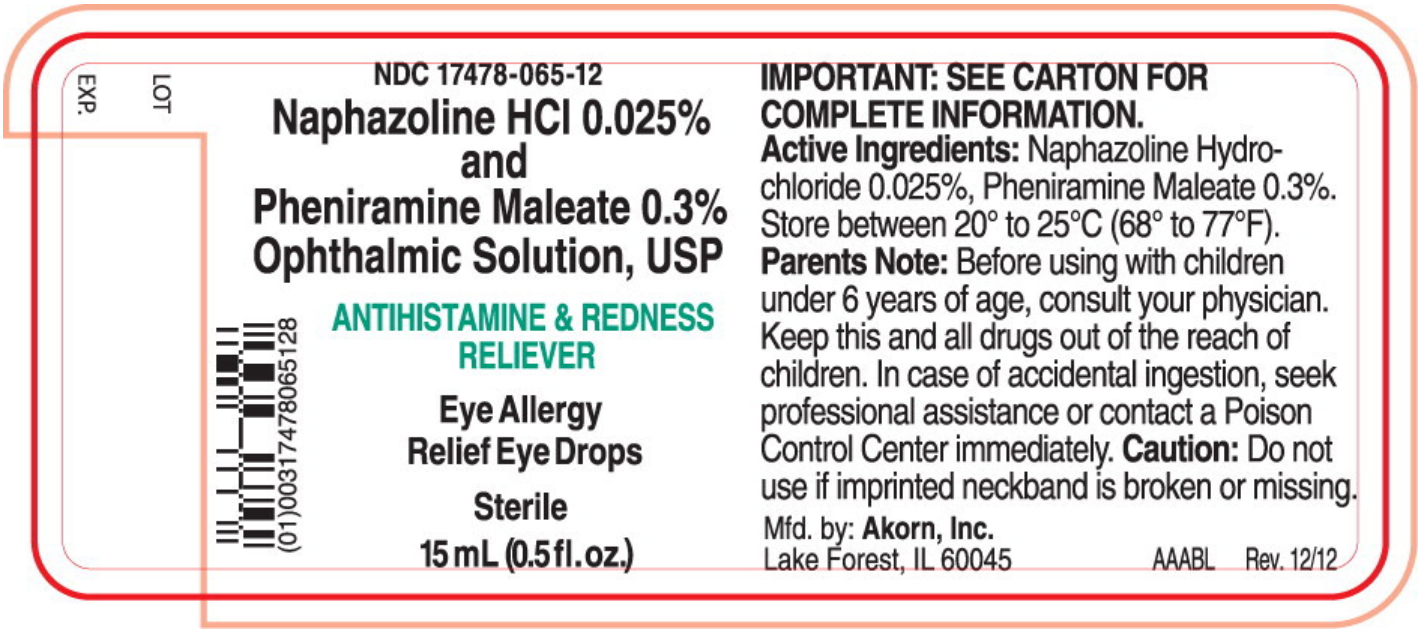
RELIEVER

Eye Allergy

Relief Eye Drops

Sterile

15 mL (0.5 fl. oz.)



Principal Display Panel Text for Carton Label:

NDC 17478-065-12

Naphazoline HCl 0.025%

and

Pheniramine Maleate 0.3%

Ophthalmic Solution, USP

ANTIHISTAMINE & REDNESS

RELIEVER

Eye Allergy

Relief Eye Drops

► Relieves Redness

► Relieves itchy Eyes Due To:

Pollen ● Ragweed ● Grass

Animal Hair & Dander

Sterile

15 mL (0.5 fl. oz.)

NAPHAZOLINE HYDROCHLORIDE AND PHENIRAMINE MALEATE

naphazoline hydrochloride and pheniramine maleate solution/ drops

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:17478-065
Route of Administration	OPHTHALMIC		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
Naphazoline Hydrochloride (UNII: MZ1131787D) (Naphazoline - UNII:H231GF11BV)	Naphazoline Hydrochloride	0.25 mg in 1 mL
Pheniramine Maleate (UNII: NYW905655B) (Pheniramine - UNII:134FM9ZZ6M)	Pheniramine Maleate	3 mg in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
Boric Acid (UNII: R57ZHV85D4)	
Sodium Borate (UNII: 91MBZ8H3QO)	
Benzalkonium Chloride (UNII: F5UM2KM3W7)	
Edetate Disodium (UNII: 7FLD91C86K)	
Sodium Hydroxide (UNII: 55X04QC32I)	
Hydrochloric Acid (UNII: QTT17582CB)	
Water (UNII: 059QF0KO0R)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:17478-065-12	1 in 1 CARTON	01/24/2013	
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	ANDA202795	01/24/2013	

Labeler - Akorn, Inc. (062649876)

Establishment

Name	Address	ID/FEI	Business Operations
Akorn, Inc		063434679	PACK(17478-065) , LABEL(17478-065)

Establishment

Name	Address	ID/FEI	Business Operations
Akorn, Inc.		155135783	MANUFACTURE(17478-065) , ANALYSIS(17478-065) , STERILIZE(17478-065)

Revised: 10/2016 Akorn, Inc.