

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 due to an enlarged prostate gland

When using this product

- pupils may become enlarged temporarily
- 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

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

- some users may experience a brief tingling sensation
- 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.)

EXP.	LOT	<p>NDC 17478-065-12</p> <p>Naphazoline HCl 0.025% and Pheniramine Maleate 0.3% Ophthalmic Solution, USP</p> <p>ANTIHISTAMINE & REDNESS RELIEVER</p> <p>Eye Allergy Relief Eye Drops</p> <p>Sterile 15 mL (0.5 fl. oz.)</p>	<p>IMPORTANT: SEE CARTON FOR COMPLETE INFORMATION.</p> <p>Active Ingredients: Naphazoline Hydrochloride 0.025%, Pheniramine Maleate 0.3%. Store between 20° to 25°C (68° to 77°F).</p> <p>Parents Note: Before using with children under 6 years of age, consult your physician. Keep this and all drugs out of the reach of children. In case of accidental ingestion, seek professional assistance or contact a Poison Control Center immediately. Caution: Do not use if imprinted neckband is broken or missing.</p> <p>Mfd. by: Akorn, Inc. Lake Forest, IL 60045</p> <p style="text-align: right;">AAABL Rev. 12/12</p>
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Ophthalmic Solution, USP

ANTIHISTAMINE & REDNESS

RELIEVER

Eye Allergy

Relief Eye Drops

► Relives 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 LABEL	Item Code (Source)	NDC:17478-065
Route of Administration	OPHTHALMIC	DEA Schedule	

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Naphazoline Hydrochloride (Naphazoline)	Naphazoline Hydrochloride	0.25 mg in 1 mL
Pheniramine Maleate (Pheniramine)	Pheniramine Maleate	3 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
Boric Acid	
Sodium Borate	
Benzalkonium Chloride	
Edetate Disodium	
Sodium Hydroxide	
Hydrochloric Acid	
Water	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:17478-065-12	1 in 1 CARTON		
1		15 mL in 1 BOTTLE, DROPPER		

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: 1/2013

Akorn, Inc.