

NAPHAZOLINE HYDROCHLORIDE AND PHENIRAMINE MALEATE- naphazoline hydrochloride and pheniramine maleate solution/ drops

Walgreens

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 becomes 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 or Comments?

1-800-932-5676

Principal Display Panel Text for Container Label:

Well at

Walgreens

NDC 0363-9650-02

STERILE

Allergy

Eye Drops

Naphazoline HCl 0.025% and

Pheniramine Maleate 0.3%

Ophthalmic Solution, USP

Antihistamine & Redness Reliever

Relieves redness & itchy eyes

0.5 FL OZ (15 mL)



Principal Display Panel Text for Carton Label:

Well at

Walgreens

NDC 0363-9650-02

WALGREENS PHARMACIST RECOMMENDED†

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itchy eyes due to:

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Compare to Visine-A[®] active ingredients#

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naphazoline hydrochloride and pheniramine maleate solution/ drops

Product Information

Product Type	HUMAN OTC DRUG LABEL	Item Code (Source)	NDC:0363-9650
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:0363-9650-02	1 in 1 CARTON		
1		15 mL in 1 BOTTLE, DROPPER; Combination Product Type = C112160		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA202795	04/23/2013	

Labeler - Walgreens (008965063)**Registrant** - Akorn, Inc. (062649876)**Establishment**

Name	Address	ID/FEI	Business Operations
Akorn, Inc		063434679	PACK(0363-9650), LABEL(0363-9650)

Establishment

Name	Address	ID/FEI	Business Operations
Akorn, Inc.		155135783	MANUFACTURE(0363-9650), ANALYSIS(0363-9650), STERILIZE(0363-9650)

Revised: 4/2013

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