

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†

STERILE

Allergy

Eye Drops

Naphazoline HCl 0.025% and

Pheniramine Maleate 0.3%

Ophthalmic Solution, USP

Antihistamine & Redness Reliever

Relieves redness &

itchy eyes due to:

- Pollen
- Ragweed • Grass
- Animal hair & dander

Compare to Visine-A[®] active ingredients#

0.5 FL OZ (15 mL)



NAPHAZOLINE HYDROCHLORIDE AND PHENIRAMINE MALEATE

naphazoline hydrochloride and pheniramine maleate solution/ drops

Product Information

| | | | |
|-------------------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:0363-9650 |
| 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: 059QF0K00R) | |

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; Type 0: Not a Combination Product | | |

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

Walgreens