EYE ALLERGY RELIEF- pheniramine maleate and naphazoline hydrochloride solution/ drops Rite Aid Corporation

Drug Facts

Active ingredients

Naphazoline HCI (0.02675%)

Pheniramine maleate (0.315%)

Purpose

Redness reliever

Antihistamine

Uses

• temporarily relieves itching and redness caused by 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
- if solution changes color or becomes cloudy

Ask a doctor before use if you have

- heart disease
- high blood pressure
- trouble urinating due to an enlarged prostate gland
- narrow angle glaucoma

When using this product

- overuse may cause more eye redness
- pupils may become enlarged temporarily
- do not touch tip of container to any surface to avoid contamination
- you may feel a brief tingling after putting drops in eye
- replace cap after use
- remove contact lenses before using

Stop use and ask a doctor if you experience

- eye pain
- changes in vision
- redness or irritation of the eye that 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 oral ingestion in infants and children may lead to coma and marked reduction in body temperature.

Directions

- Adults and children 6 years of age and older: Instill 1 or 2 drops in the affected eye(s) up to 4 times daily.
- Children under 6 years: ask a doctor

Other information

- store at 20°-25° C (68°-77° F)
- This package is child-resistant
- protect from light
- use before expiration date marked on the carton or bottle

Inactive ingredients

benzalkonium chloride, boric acid, edetate disodium, hypromellose, purified water, sodium borate, sodium chloride. Hydrochloric acid may be used to adjust pH.

Questions or comments?

Call: 1-866-767-8975

Package/Label Principal Display Panel



Compare to Opcon-A active ingredients*

NDC 11822-0552-1

eye allergy relief drops

Pheniramine Maleate 0.315% and

Naphazoline

Hydrochloride 0.02675%

Ophthalmic Solution

Itching and Redness Reliever Eye Drops

Sterile

0.5 FL OZ (15 mL)

EYE ALLERGY RELIEF

pheniramine maleate and naphazoline hydrochloride solution/ drops

| Product Information | | | |
|-------------------------|----------------|--------------------|----------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:11822-0552 |
| Route of Administration | OPHTHALMIC | | |

| Active Ingredient/Active Moiety | | | | |
|---|-------------------------------|----------------------|--|--|
| Ingredient Name | Basis of Strength | Strength | | |
| NAPHAZOLINE HYDROCHLORIDE (UNII: MZ1131787D) (NAPHAZOLINE - UNII: H231GF11BV) | NAPHAZ OLINE HYDROCHLORIDE | 0.2675 mg in 1 mL | | |
| PHENIRAMINE MALEATE (UNII: NYW905655B) (PHENIRAMINE - UNII:134FM9ZZ6M) | PHENIRAMINE MALEATE | 3.15 mg in 1 mL | | |

| Inactive Ingredients | | |
|--|----------|--|
| Ingredient Name | Strength | |
| BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) | | |
| BORIC ACID (UNII: R57ZHV85D4) | | |
| EDETATE DISODIUM (UNII: 7FLD91C86K) | | |
| HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO) | | |
| WATER (UNII: 059QF0KO0R) | | |
| SODIUM BORATE (UNII: 91MBZ8H3QO) | | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | | |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | | |

| Packaging | | | | |
|-----------|----------------------|---|-------------------------|-----------------------|
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:11822- 0552-1 | 1 in 1 CARTON | 07/01/2015 | |
| 1 | | 15 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product | | |
| 2 | NDC:11822- 0552-2 | 2 in 1 CARTON | 07/01/2015 | |
| 2 | | 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 |
| NDA | NDA020065 | 07/01/2015 | |
| | | | |

Labeler - Rite Aid Corporation (014578892)

Registrant - Bausch & Lomb Incorporated (196603781)

| Establishment | | | | |
|----------------------------|---------|-----------|----------------------------|--|
| Name | Address | ID/FEI | Business Operations | |
| Bausch & Lomb Incorporated | | 079587625 | MANUFACTURE(11822-0552) | |

| Establishment | | | | |
|--------------------|---------|-----------|-----------------------------|--|
| Name | Address | ID/FEI | Business Operations | |
| Loba Feinchemie AG | | 300137478 | API MANUFACTURE(11822-0552) | |

Revised: 9/2021 Rite Aid Corporation