FAMILY CARE REDNESS RELIEF- glycerin and naphazoline hcl solution/ drops United Exchange Corp.

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Family Care Maximum Redness Relief Eye Drops 0.5oz 645, 2019 DW

Active ingredients Purposes

Glycerin 0.5%.....Eye lubricant

Naphazoline HCl 0.03.....Eye redness reliever

Uses

- Ifor the relief of redness of the eye due to minor eye irritations
- for the temporary relief of burning and irritation due to dryness of the eye
- for use as a protectant against further irritation or to relieve dryness of the eye

Warnings

For external use only

Do not use if this solution changes color or becomes cloudy.

Ask a doctor before use if you have narrow angle glaucoma.

When using this product

- do not touch tip of container to any surface to avoid contamination
- replace cap after each use
- pupils may become enlarged temporarily
- overuse may cause more eye redness
- remove contact lenses before using

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

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center (1-800-222-1222) right away.

Directions

- to open bottle, push cap down and twist counterclockwise
- instill 1 to 2 drops in the affected eye(s) up to 4 times daily
- children under 6 years of age: ask a doctor

Other information

• store at room temperature 15-25°F (59-77°F)

Inactive ingredients

benzalkonium chloride, boric acid, edetate disodium, purified water, sodium borate

Distributed by:

United Exchange Corp.

Cypress, CA 90630 USA

Made in South Korea



FAMILY CARE REDNESS RELIEF

glycerin and naphazoline hcl solution/ drops

| Product Information | | | |
|-------------------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:65923-645 |
| Route of Administration | OPHTHALMIC | | |

| Active Ingredient/Active Moiety | | | |
|---|------------------------------|-------------------|--|
| Ingredient Name | Basis of Strength | Strength | |
| NAPHAZOLINE HYDRO CHLORIDE (UNII: MZ1131787D) (NAPHAZOLINE - UNII: H231GF11BV) | NAPHAZOLINE HYDROCHLORIDE | 0.3 mg in 1 mL | |
| GLYCERIN (UNII: PDC6A3C0OX) (GLYCERIN - UNII:PDC6A3C0OX) | GLYCERIN | 5 mg in 1 mL | |

| Inactive Ingredients | |
|--|----------|
| Ingredient Name | Strength |
| BORIC ACID (UNII: R57ZHV85D4) | |
| EDETATE DISO DIUM (UNII: 7FLD91C86K) | |
| WATER (UNII: 059QF0KO0R) | |
| SODIUM BORATE (UNII: 91MBZ8H3QO) | |
| BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) | |

| P | Packaging | | | |
|---|----------------------|---|-------------------------|-----------------------|
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:65923-645- 15 | 1 in 1 CARTON | 12/12/2019 | |
| 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 | |
| OTC monograph final | part349 | 12/12/20 19 | | |
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Labeler - United Exchange Corp. (840130579)

Revised: 1/2020 United Exchange Corp.