DG MAXIMUM STRENGTH REDNESS RELIEF- glycerin, naphazoline hcl solution K.C. Pharmaceuticals, Inc.

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.

DG Health Maximum Strength Redness Relief

Active ingredients

Glycerin 0.5%

Naphazoline hydrochloride 0.03%

Purposes

Glycerin ----Lubricant

Naphazoline hydrochloride ----Redness reliever

Uses

- For 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 dryness of the eye

Warnings

For external use only

Do not use if solution changes color or becomes cloudy

Ask a doctor before use if you have narrow angle glaucoma

When using this product

- To avoid contamination, do not touch tip of container to any surface
- Replace cap after using
- Overuse may produce increased redness of the eye
- Pupils may become enlarged temporarily

Stop use and ask a doctor if

- you experience eye pain
- you experience changes in vision
- you experience continued redness or irritation of the eye
- the condition worsens or persists for more than 72 hours

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

Instill 1 or 2 drops in the affected eye(s) up to 4 times daily.

Other information

• store at room temperature

- remove contact lenses before using
- **Tamper Evident:** Do not use this product if imprinted neckband is missing or broken.

Inactive ingredients

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



DG MAXIMUM STRENGTH REDNESS RELIEF

glycerin, naphazoline hcl solution

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55651-870
Route of Administration	OPHTHALMIC		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
GLYCERIN (UNII: PDC6A3C0OX) (GLYCERIN - UNII:PDC6A3C0OX)	GLYCERIN	0.5 g in 100 mL
NAPHAZOLINE HYDROCHLORIDE (UNII: MZ1131787D) (NAPHAZOLINE - UNII: H231GF11BV)	NAPHAZ OLINE HYDROCHLORIDE	0.03 g in 100 mL

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

P	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55651- 870-01	1 in 1 CARTON	01/31/2020	
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	01/31/2020		

Labeler - K.C. Pharmaceuticals, Inc. (174450460)

Registrant - K.C. Pharmaceuticals, Inc. (174450460)

Establishment			
Name	Address	ID/FEI	Business Operations
K.C. Pharmaceuticals, Inc.		174450460	manufacture(55651-870) , pack(55651-870) , label(55651-870)

Revised: 12/2022 K.C. Pharmaceuticals, Inc.