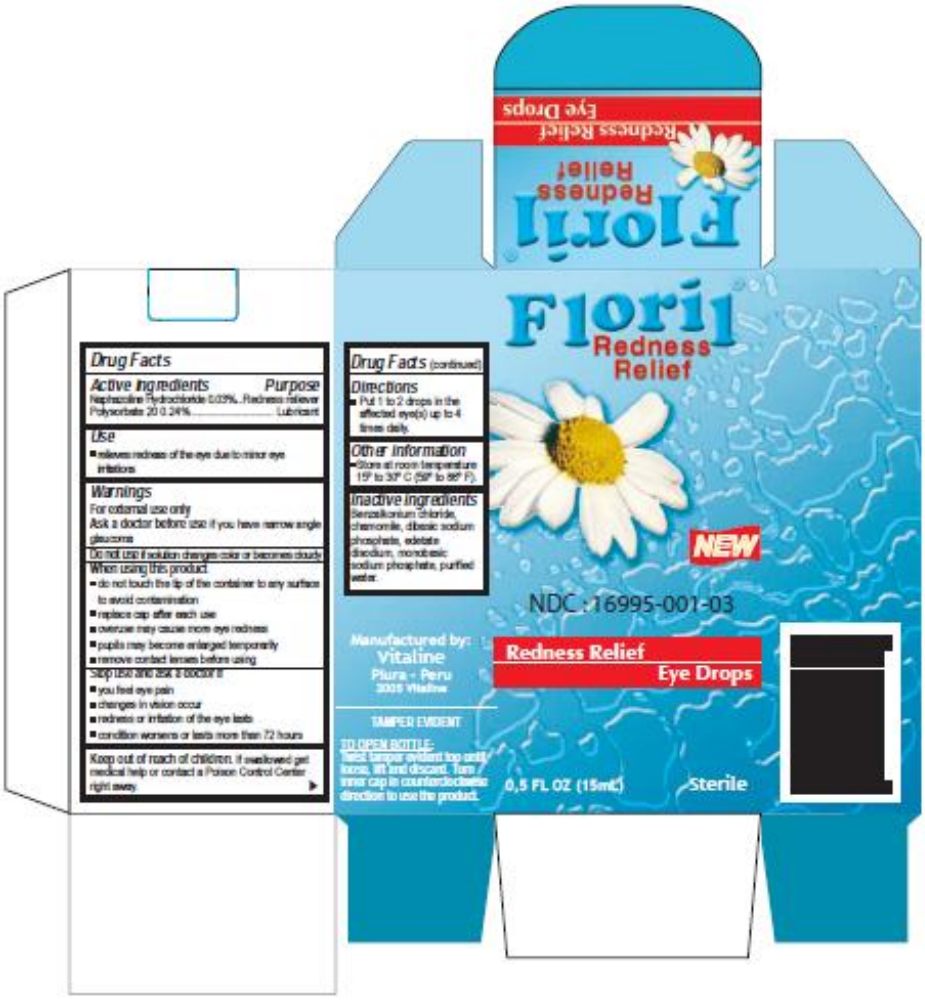
FLORIL REDNESS RELIEF - naphazoline hydrochloride solution/ drops
VITALINE S.A.C.

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.



Actives ingredients Purpose

Naphazoline Hydrocloride 0,03% redness reliever
Polysorbate 20 0,24% Lubricant

Inactive ingredients

Benzalkonium chloride, chamomile, dibasic sodium phosphate, edetate disodium, monobasic sodium phosphate, purified water.

WARNINGS

For external use only

Ask a doctor before use if you have narrow angle glaucoma

Do not use if the solution changes color or becomes cloudy

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

Stop use and ask 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 swallowed get medical help or contact a Poison Control Center right away

Use

Relieves redness of the eye due to minor eye irritations

Directions

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

Other information

Store at room temperature 15° to 30° (59° to 86° F).

FLORIL REDNESS RELIEF

naphazoline hydrochloride solution/ drops

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:16995-001
Route of Administration	OPHTHALMIC		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
NAPHAZOLINE HYDROCHLORIDE (UNII: MZ1131787D) (NAPHAZOLINE - UNII:H231GF11BV)	NAPHAZOLINE HYDROCHLORIDE	3 mg in 10 mL
POLYSORBATE 20 (UNII: 7T1F30V5YH) (POLYSORBATE 20 - UNII:7T1F30V5YH)	POLYSORBATE 20	2 mg in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
LIME (UNII: C7X2M0VVNH)	353 mg in 10000 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:16995-001-01	3 mL in 1 BOTTLE, DROPPER		
2	NDC:16995-001-02	10 mL in 1 BOTTLE, DROPPER		
3	NDC:16995-001-03	15 mL in 1 BOTTLE, DROPPER		
4	NDC:16995-001-04	30 mL in 1 BOTTLE, DROPPER		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part349	11/10/2005	

Labeler - VITALINE S.A.C. (954343687)

Revised: 1/2010 VITALINE S.A.C.