

FLORIL TEARS - polyvinyl alcohol 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.

Floril TEARS



Active ingredients Purpose

Polyvinyl Alcohol 1,4% Lubricant

Polyethylene Glycol 400 0,2% Lubricant

When using this product

- do not touch the tip of the container to any surface to avoid contamination
- replace cap after each use
- remove contact lenses before using

Stop use and ask a doctor if

- You feel eye pain
- changes in vision occur
- 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.

Inactive ingredients

Benzalkonium chloride, dibasic sodium phosphate, edetate disodium, monobasic sodium phosphate, polysorbate 80, sodium chloride, purified water.

WARNINGS

For external use only.

Do not use if the solution changes color or become cloudy.

Directions

- Put 1 to 2 drops in the affected eyes up to times daily.

Other information

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Uses

- temporary relief of eye dryness and redness due to insufficient production of tears.
- prevents further irritation.

FLORIL TEARS			
polyvinyl alcohol solution/ drops			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:16995-002
Route of Administration	OPHTHALMIC		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
POLYVINYL ALCOHOL (UNII: 532B59J990) (POLYVINYL ALCOHOL - UNII:532B59J990)		POLYVINYL ALCOHOL	14 mL in 1 mL

POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ) (POLYETHYLENE GLYCOL 400 - UNII:B697894SGQ)

POLYETHYLENE
GLYCOL 400

2 mg
in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:16995-002-01	3 mL in 1 BOTTLE, DROPPER		
2	NDC:16995-002-02	10 mL in 1 BOTTLE, DROPPER		
3	NDC:16995-002-03	15 mL in 1 BOTTLE, DROPPER		
4	NDC:16995-002-04	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 - VIT ALINE S.A.C. (954343687)

Revised: 1/2010

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