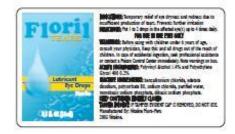
# FLORIL TEARS - polyvinyl alcohol solution/ drops VITALINE S.A.C.

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.

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#### 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 our 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				

l	Active Ingredient/Active Moiety				
ı	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: 059QF0KO0R)

P	ackaging					
#	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 - VITALINE S.A.C. (954343687)

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