

**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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Active ingredients    Purpose

Polyvinyl Alcohol 1,4%    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, polyethylene glycol 300, 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**

Enter section text here

**Uses**

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



**Drug Facts**

Active ingredients	Purpose
Polyvinyl Alcohol 1.4% .....	Lubricant
Polyethylene Glycol 400 0.2% .....	Lubricant

**Uses**

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

**Warnings**  
For external use only.  
Do not use if solution changes color or becomes cloudy.

**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.

**Directions**

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

**Drug Facts (continued)**

**Other information**

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

**Inactive ingredients**

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

Manufactured by:  
**Vitaline**  
Piura - Peru  
2010 Vitaline

NCD: 16995-002-03

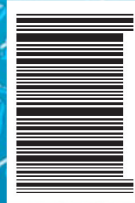
**Lubricant**  
**Eye Drops**

TAMPER EVIDENT

**TO OPEN BOTTLE:**  
Twist tamper evident top until loose, lift and discard. Turn inner cap in counterclockwise direction to use the product.

0,5 FL OZ (15mL)

Sterile



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## FLORIL TEARS

polyvinyl alcohol solution/ drops

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:16995-004
<b>Route of Administration</b>	OPHTHALMIC		

### Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
POLYVINYL ALCOHOL (UNII: 532B59J990) (POLYVINYL ALCOHOL - UNII:532B59J990)	POLYVINYL ALCOHOL	14 mg in 1 mL

### Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
WATER (UNII: 059QF0K00R)	
POLYETHYLENE GLYCOL 300 (UNII: 5655G9Y8AQ)	2 mg in 1 mL

### Packaging

#	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:16995-004-01	3 mL in 1 BOTTLE, DROPPER		
2	NDC:16995-004-02	10 mL in 1 BOTTLE, DROPPER		
3	NDC:16995-004-03	15 mL in 1 BOTTLE, DROPPER		
4	NDC:16995-004-04	30 mL in 1 BOTTLE, DROPPER		

### Marketing Information

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

**Labeler** - VIT ALINE S.A.C. (954343687)

Revised: 6/2010

VITALINE S.A.C.