## VIVA - polysorbate 80 solution/ drops Dakota Laboratories, LLC

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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## **Drug Facts**

# Active ingredients

Polysorbate 80 (1.0%)

# Purpose

Eye Lubricant

# Keep out of reach of children

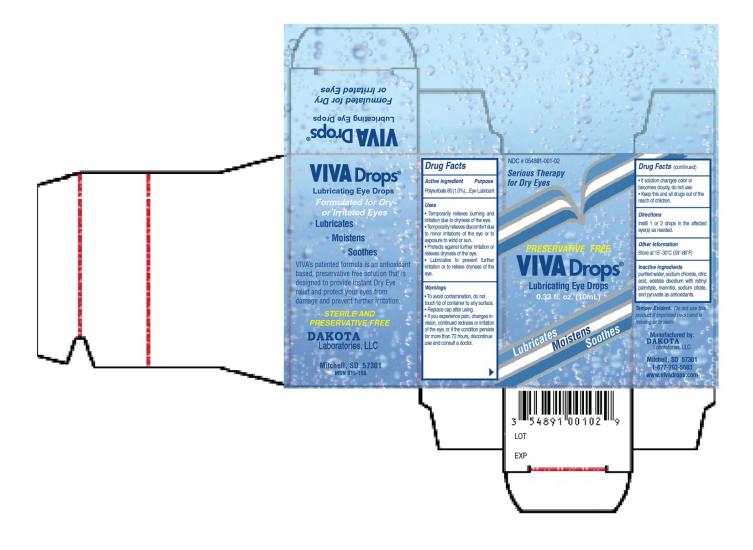
- Keep this and all drugs out of the reach of children.
- Temporarily relieves burning and irritation due to dryness of the eye.
- Temporarily relieves discomfort due to minor irritations of the eye or to exposure to wind or sun.
- Protects against further irritation or relieves dryness of the eye.
- Lubricates to prevent further irritation or to relieve dryness of the eye.
- To avoid contamination, do not touch tip of container to any surface.
- Replace cap after using

• If you experience pain, changes in vision, continued redness or irritation of the eye, or if the condition persists for more than 72 hours, discontinue use and consult a doctor.

• If solution changes color or becomes cloudy, do not use.

Instill 1 or 2 drops in the affected eye(s) as needed.

purified water, sodium chloride, citric acid, edetate disodium with retinyl palmitate, mannitol, sodium citrate, and pyruvate as antioxidants.







### **Drug Facts**

Active Ingredient (In each unit dose): Polysorbate 80 (1.0%)

### Purpose: Eye Lubricant

#### Uses

- Temporarily relieves burning and irritation due to dryness of the eye.
- Temporarily relieves discomfort due to minor irritations of the eye or to exposure to wind or sun.
- Protects against further irritation or relieves dryness of the eye.
- Lubricates to prevent further irritation or to relieve dryness of the eve.

#### Warnings

 To avoid contamination, do not touch tip of container to any surface.

Do not reuse. Once opened

### Drug Facts (continued)

- Warnings (continued) • If solution changes color or
- becomes cloudy, do not use.
- Keep this and all drugs out of the reach of children.

### Directions

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 To open, twist tab top completely off.
Instill 1 or 2 drops in the affected eye(s) as needed.

#### Other Information

Store at 15'-30°C (59'-86'F)

### Inactive Ingredients

Purified water, sodium chloride, citric acid, edetate disodium with retinyl palmitate, mannitol, sodium citrate, and sodium pyruvate as antioxidants.

### discard.

 If you experience pain, changes in vision continued redness or irritation of the eye, or if the condition persists for more than 72 hours, discontinue use and consult a doctor.

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Manufactured by: DAKOTA Laboratories, LLC Mitchell, SD 57301 1-877-793-5683 vivadrops.com

# VIVA

polysorbate 80 solution/ drops

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:54891-001
Route of Administration	OPHTHALMIC		

Active Ingredient/Active Moiety				
Ingredient Name	<b>Basis of Strength</b>	Strength		
Polysorbate 80 (UNII: 6OZP39ZG8H) (Sorbitan - UNII:6O92ICV9RU)	Polysorbate 80	100 mg in 10 mL		

### **Inactive Ingredients**

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	60.5 mg in 10 mL
Citric Acid (UNII: 2968PHW8QP)	.34 mg in 10 mL
Edetate Disodium (UNII: 7FLD91C86K)	5 mg in 10 mL
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)	5.5 mg in 10 mL
Mannitol (UNII: 30WL53L36A)	18 mg in 10 mL
Sodium Citrate (UNII: 1Q73Q2JULR)	73.6 mg in 10 mL
Sodium Pyruvate (UNII: POD38AIF08)	5 mg in 10 mL

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#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54891-001-02	10 mL in 1 BOTTLE		
2	NDC:54891-001-04	.5 mL in 1 VIAL, SINGLE-USE		
3	NDC:54891-001-03	.5 mL in 1 VIAL, SINGLE-USE		

Marketing Information				
Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
part349	02/19/1987			
	Application Number or Monograph Citation	Application Number or Monograph Citation Marketing Start Date		

Establishment				
Name	Address	ID/FEI	<b>Business Operations</b>	
Dakota Laboratories, LLC		002303871	manufacture	

Revised: 1/2012

Dakota Laboratories, LLC