

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.

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.

VIVA Drops[®]
Lubricating Eye Drops
Formulated for Dry
or Irritated Eyes

VIVA Drops[®]
Lubricating Eye Drops
Formulated for Dry
or Irritated Eyes

- Lubricates
- Moistens
- Soothes

VIVA's patented formula is an antioxidant based, preservative free solution that is designed to provide instant Dry Eye relief and protect your eyes from damage and prevent further irritation.

**STERILE AND
PRESERVATIVE FREE**

**DAKOTA
Laboratories, LLC**

Mitchell, SD 57301
MSN 015-198

Drug Facts

Active Ingredient	Purpose
Polysorbate 80 (1.0%)...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.
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Warnings

- To avoid contamination, do not touch tip of container to any surface.
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NDC # 054891-001-02

**Serious Therapy
for Dry Eyes**

PRESERVATIVE FREE
VIVA Drops[®]
Lubricating Eye Drops
0.33 fl. oz. (10mL)

**Lubricates
Moistens
Soothes**

Drug Facts (continued)

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

Directions
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 pyruvate as antioxidants.

Tamper Evident. Do not use this product if imprinted neckband is missing or broken.

Manufactured by:
**DAKOTA
Laboratories, LLC**

Mitchell, SD 57301
1-877-703-5683
www.vivadrops.com



LOT

EXP



Drug Facts

Active Ingredient (In each unit dose)	Purpose
Polysorbate 80 (1.0%)	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 eye.

Warnings

- To avoid contamination, do not touch tip of container to any surface.
- Do not reuse. Once opened 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.
- If solution changes color or becomes cloudy, do not use.
- Keep this and all drugs out of the reach of children.

NDC # 054891-001-04
Serious Therapy for Dry Eyes

20 Sterile Single-Use Containers

PRESERVATIVE FREE

VIVA Drops®
 Lubricating Eye Drops

Lubricates • Moistens • Soothes

0.5 ml / 0.017 fl oz each (0.33 fl oz total)

Drug Facts (continued)

Directions

- 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, edelate disodium with retinyl palmitate, mannitol, sodium citrate, and sodium pyruvate as antioxidants.

Manufactured by:
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 Laboratories, LLC

Mitchell, SD 57301
 1-877-793-5683
 vivadrops.com

VIVA Drops®
 Lubricating Eye Drops

Formulated for Dry or Irritated Eyes

VIVA's patented formula is an antioxidant based, preservative free solution that is designed to provide instant Dry Eye relief and protect your eyes from damage and prevent further irritation.

STERILE AND PRESERVATIVE FREE

Lubricates • Moistens • Soothes

DAKOTA
 Laboratories, LLC
 Mitchell, SD 57301
 MSN 215-038

LOT
 EXP



NDC # 054891-001-03

**2 Sterile
Single-Use
Containers**

PRESERVATIVE FREE

VIVA Drops®

Lubricating Eye Drops

Lubricates
Moistens
Soothes

vivadrops.com

0.5 ml / 0.017 fl oz each
(0.033 fl oz total)

**Serious Therapy
for Dry Eyes**

**STERILE AND
PRESERVATIVE FREE**

VIVA's patented formula is an antioxidant based, preservative free solution that is designed to provide instant Dry Eye relief and protect your eyes from damage and prevent further irritation.

DAKOTA
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Mitchell, SD 57301

1-877-793-5683
vivadrops.com

MSN 215-039

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 eye.

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

- **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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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	Basis of Strength	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: 3OWL53L36A)	18 mg in 10 mL
Sodium Citrate (UNII: 1Q73Q2JULR)	73.6 mg in 10 mL
Sodium Pyruvate (UNII: POD38AIF08)	5 mg in 10 mL

Packaging

#	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

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part349	02/19/1987	

Labeler - Dakota Laboratories, LLC (002303871)

Establishment

Name	Address	ID/FEI	Business Operations
Dakota Laboratories, LLC		002303871	manufacture

Revised: 1/2012

Dakota Laboratories, LLC