# ARTIFICIAL TEARS- mineral oil and white petrolatum ointment Akorn Animal Health, Inc.

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

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#### **Drug Facts**

## **Active ingredients**

Mineral Oil 15%

White Petrolatum 83%

### Purpose

Eye lubricant

Eye lubricant

#### Uses

For use as a lubricant to prevent further irritation or to relieve dryness of the eye(s).

#### **Warnings**

- For external use only.
- To avoid contamination, do not touch tip of container to any surface.
- Replace cap after using.

Stop use and ask a doctor if condition persists or increases discontinue use and consult veterinarian.

**Keep out of the reach of children.** If swallowed, get medical help or contact a Poison Control Center right away.

#### **Directions**

Pull down lower lid of the affected eye(s) and apply small amount (one-fourth inch) of ointment to the inside of the eyelid, one or more times daily, or as directed by a doctor.

#### Other information

- Store at 20° to 25°C (68° to 77°F)
  [see USP controlled Room Temperature].
- Store away from heat.
- Protect from freezing.
- Keep tightly closed.
- See crimp for Control Number and Expiration Date.
- RETAIN THIS CARTON FOR FUTURE REFERENCE.

#### **Inactive ingredient**

Lanolin 2%

Principal Display Panel Text for Container Label:

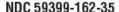
NDC 59399-162-35 Akorn Animal Health Logo

3.5 g

ARTIFICIAL TEARS

Lubricant Ophthalmic Ointment FOR OPHTHALMIC USE ONLY

For Veterinary Use Net Wt 3.5g (1/8 oz) Sterile







# **ARTIFICIAL TEARS**

Lubricant Ophthalmic Ointment

FOR OPHTHALMIC USE ONLY

## For Veterinary Use

Net Wt 3.5g (1/8 oz) Sterile

READ OUTER CARTON FOR INFORMATION BEFORE USING.

Active ingredients: Mineral Oil 15%, and White Petrolatum 83%. Inactive ingredient: Lanolin 2%. USES: For use as a lubricant to prevent further irritation or to relieve dryness of the eye(s). DIRECTIONS: Pull down the lower lid of the affected eye(s) and apply a small amount (one-fourth inch) of ointment to the inside of the eyelid, one or more times daily, or as directed by a doctor.

See crimp of tube for Control No. and Exp. Date.

STORAGE: Store at 20° to 25°C (68° to 77°F) [see USP Controlled

Room Temperature]. KEEP TIGHTLY CLOSED.

WARNING: KEEP OUT OF THE REACH OF CHILDREN.

DO NOT USE IF BOTTOM RIDGE OF TUBE CAP IS EXPOSED.

Manufactured by:

Akorn, Inc., Lake Forest, IL 60045 www.akorn.com

NJATOAL Rev. 10/13

(01) 00359399162357

Principal Display Panel Text for Carton Label:

NDC 59399-162-35

Akorn Animal Health Logo

3.5 g

**ARTIFICIAL** 

**TEARS** 

Lubricant Ophthalmic

**Ointment** 

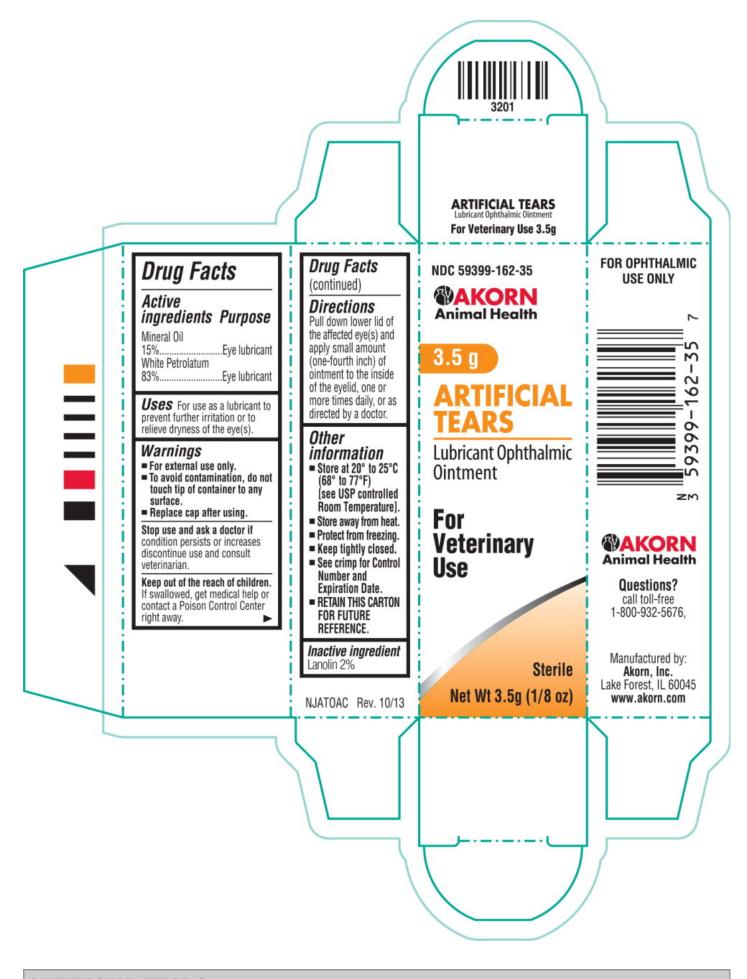
For

Veterinary

Use

Sterile

Net Wt 3.5g (1/8 oz)



## mineral oil and white petrolatum ointment

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|-----|------|-------|------------|
| Pro | duct | Intor | mation     |
| 110 | иись |       | IIIA LIVII |

| Product Type | OTC ANIMAL DRUG | Item Code (Source) | NDC:59399-162 |
|--------------|-----------------|--------------------|---------------|

Route of Administration OPHTHALMIC

### **Active Ingredient/Active Moiety**

| Ingredient Name  | Basis of Strength | Strength      |
|--|-------------------|---------------|
| Mineral Oil (UNII: T5L8T28FGP) (Mineral Oil - UNII:T5L8T28FGP) | Mineral Oil       | 150 mg in 1 g |
| Petrolatum (UNII: 4T6H12BN9U) (Petrolatum - UNII:4T6H12BN9U)   | Petro latum       | 830 mg in 1 g |

## **Inactive Ingredients**

| Ingredient Name | Strength |
|-----------------|----------|
| Ingredient Name | Strength |

Lanolin (UNII: 7EV65EAW6H)

## **Packaging**

| # Item Code        | Package Description | Marketing Start Date | Marketing End Date |
|--------------------|---------------------|----------------------|--------------------|
| 1 NDC:59399-162-35 | 1 in 1 CARTON       |                      |                    |
| 1                  | 3.5 g in 1 TUBE     |                      |                    |

# **Marketing Information**

| Marketing Category    | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-----------------------|--|----------------------|--------------------|
| Unapproved drug other |  | 06/15/2015           |                    |
|                       |  |                      |                    |

## Labeler - Akorn Animal Health, Inc. (078876357)

## Establishment

| Name       | Address | ID/FEI    | Business Operations                           |
|------------|---------|-----------|---|
| Akorn, Inc |         | 603980319 | MANUFACTURE, ANALYSIS, STERILIZE, PACK, LABEL |

## **Establishment**

| Listabilishinent  |         |           |                     |  |
|-------------------|---------|-----------|---------------------|--|
| Name              | Address | ID/FEI    | Business Operations |  |
| Croda Europe Ltd. |         | 220690285 | API MANUFACTURE     |  |

Revised: 6/2015 Akorn Animal Health, Inc.