

**TEARS AGAIN OPHT- mineral oil, white petrolatum ointment
OCuSOFT, Inc.**

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.

Tears Again Eye Ointment

OTC - ACTIVE INGREDIENT SECTION

Mineral oil (20%)
White Petrolatum (80%)

OTC - PURPOSE SECTION

Eye lubricant

INDICATIONS & USAGE SECTION

A lubricant to prevent further irritation or to relieve dryness of the eye(s).

WARNINGS SECTION

For use in the eyes only.

OTC - WHEN USING SECTION

When using this product

- do not touch tip of container to any surface to avoid contamination.
- replace cap after use.

OTC - ASK DOCTOR SECTION

Stop use and ask a doctor if

- you experience eye pain, changes in vision, continued redness or irritation of the eye.
- the condition worsens or persists for more than 72 hours.

OTC - KEEP OUT OF REACH OF CHILDREN SECTION

Keep out of reach of children.
If swallowed, get medical help or contact a Poison Control Center immediately.

DOSAGE & ADMINISTRATION SECTION

Directions

- Pull down the lower lid of the affected eye(s).
- Apply a small amount (1/4 inch) of ointment to the inside of the eyelid.

OTHER SAFETY INFORMATION

Other information

- Do not use if cap breakaway seal is broken or missing.

- Store between 15° -30°C (59° -86°F).
- Keep this carton for full product information.

OTC - QUESTIONS SECTION

Questions?

□ Call

(800)233-5469 M-F

8:30AM-5:00PM CST

or visit www.ocusoft.com

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL



TEARS AGAIN OPHT

mineral oil, white petrolatum ointment

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:54799-906

Route of Administration	OPHTHALMIC
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Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
Mineral Oil (UNII: T5L8T28FGP) (Mineral Oil - UNII:T5L8T28FGP)	Mineral Oil	200 mg in 1 g
Petrolatum (UNII: 4T6H12BN9U) (Petrolatum - UNII:4T6H12BN9U)	Petrolatum	800 mg in 1 g

Inactive Ingredients	
Ingredient Name	Strength
Water (UNII: 059QF0KO0R)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54799-906-35	5 g in 1 TUBE; Type 0: Not a Combination Product	09/01/2013	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	09/01/2013	

Labeler - OCuSOFT, Inc. (174939207)

Establishment			
Name	Address	ID/FEI	Business Operations
Galentic Pharma (India) Private Limited		650970176	manufacture(54799-906)

Revised: 3/2019

OCuSOFT, Inc.