

SYSTANE NIGHTTIME- mineral oil and white petrolatum ointment
Alcon Laboratories, 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.

Systane® Nighttime

Drug Facts

OTC - ACTIVE INGREDIENT SECTION

Mineral Oil 3%
White Petrolatum 94%

OTC - PURPOSE SECTION

Lubricant

INDICATIONS & USAGE SECTION

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

WARNINGS SECTION

For external use only

OTC - DO NOT USE SECTION

- if you are sensitive to any ingredient in this product

OTC - WHEN USING SECTION

- remove contact lenses before using
- to avoid contamination, do not touch tip of container to any surface
- replace cap after using

OTC - STOP USE SECTION AND ASK A DOCTOR IF

- you feel eye pain
- changes in vision occur
- redness or irritation of the eye(s) gets worse, persists or lasts more than 72 hours

OTC - KEEP OUT OF REACH OF CHILDREN SECTION

If swallowed, get medical help or contact a Poison Control Center right away.

DOSAGE & ADMINISTRATION SECTION

Pull down the lower lid of the affected eye and apply a small amount (one-fourth inch) of ointment to the inside of the eyelid.

OTHER INFORMATION

- Store at 8°-27°C (46°-80°F).

INACTIVE INGREDIENT SECTION

Anhydrous Liquid Lanolin 3%.

OTC - QUESTIONS SECTION

In the U.S., call 1-800-757-9195 or visit www.systane.com

PRINCIPAL DISPLAY PANEL

FOR NIGHTTIME PROTECTION OF DRY EYES

Systane®

NIGHTTIME

LUBRICANT EYE OINTMENT

OVERNIGHT RELIEF

DRY EYE THERAPY

Systane®

NIGHTTIME

LUBRICANT EYE OINTMENT

Systane® Nighttime Lubricant Eye Ointment is a safe and effective formulation with no preservatives. This unpreserved ointment, when applied to the eyes, forms a smooth comfortable protective film, especially useful for nighttime protection and lubrication of dry eyes.

PRESERVATIVE-FREE

Alcon®

STERILE

3.5 g Tube (1/8 OZ NET WT)

Systane[®]

NIGHTTIME

LUBRICANT EYE OINTMENT

OVERNIGHT RELIEF

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FOR
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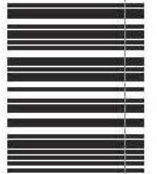
Alcon[®]

STERILE

3.5 g Tube (1/8 OZ NET WT)

509/47868-1
509/47868-1
509/47868-1
509/47868-1

LOT:
EXP.:



TAMPER EVIDENT: Prior to use, inspect the product container. If "skirt" on bottom of cap is visible, do not use.

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Made in Belgium.

509/47868-1

06-2009

82.5 X 19.5 X 29.5 mm

Directions
Pull down the lower lid of the affected eye and apply a small amount (one-fourth inch) of ointment to the inside of the eyelid.

Other information
Store at 8°-27°C (46°-80°F).

Inactive ingredient
Anhydrous Liquid Lanolin 3%.

Questions?
In the U.S., call 1-800-757-9195 or visit www.systane.com

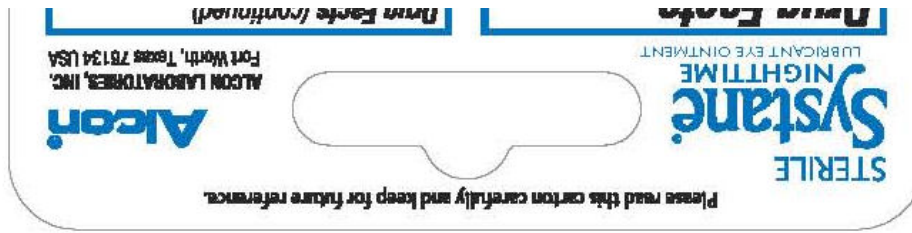
Warnings
For external use only
Do not use
If you are sensitive to any ingredient in this product

When using this product
remove contact lenses before using
to avoid contamination, do not touch tip of container to any surface
replace cap after using

Stop use and ask a doctor if
you feel eye pain
changes in vision occur

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

Active ingredients
Mineral Oil 3% Lubricant
White Petroleum 84% Lubricant



SYSTANE NIGHTTIME

mineral oil and white petrolatum ointment

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0065-0509
Route of Administration	OPHTHALMIC		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Mineral Oil (UNII: T5L8T28FGP) (Mineral Oil - UNII:T5L8T28FGP)	Mineral Oil	30 mg in 1 g
Petrolatum (UNII: 4T6H12BN9U) (Petrolatum - UNII:4T6H12BN9U)	Petrolatum	940 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
Lanolin (UNII: 7EV65EAW6H)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0065-0509-35	1 in 1 CARTON	06/26/2008	
1		3.5 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part349	06/26/2008	

Labeler - Alcon Laboratories, Inc. (008018525)

Registrant - Alcon Laboratories, Inc. (008018525)

Establishment

Name	Address	ID/FEI	Business Operations
S.A. Alcon-Couvreur N.V.		370205429	manufacture(0065-0509)

