

**GENTEAL NIGHT-TIME PM- white petrolatum ointment**  
**Novartis Pharmaceutical Corporation**

*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**

**OTC - ACTIVE INGREDIENT SECTION**

Mineral oil (15%)  
White petrolatum (85%)

**OTC - PURPOSE SECTION**

Lubricant

**INDICATIONS & USAGE SECTION**

- Relieves dryness of the eye.
- Temporarily relieves discomfort due to minor irritations of the eye or from exposure to wind or sun.
- As a protectant against further irritation.

**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**

**When using this product** do not touch tip of container to any surface. Replace cap after using.

**OTC - STOP USE SECTION**

**Stop use and ask a doctor if** you experience any of the following:

- eye pain
- changes in vision
- continued redness or irritation of the eye
- condition worsens or persists for 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 SAFETY INFORMATION**

Store between 15° - 25°C (59° - 77°F).

## **INACTIVE INGREDIENT SECTION**

anhydrous liquid lanolin

## **OTC - QUESTIONS SECTION**

In the U.S. call toll-free **1-866-393-6336**; [MedInfo@AlconLabs.com](mailto:MedInfo@AlconLabs.com)

Serious side effects associated with use of this product may be reported to this telephone number.  
[www.genteal.com](http://www.genteal.com)

## **PRINCIPAL DISPLAY PANEL**

NDC 0078-0473-97

### **Night-time PM**

Dry Eye Relief

### **GenTeal®**

LUBRICANT EYE OINTMENT

GenTeal® Night-time PM ointment provides long-lasting relief for night-time comfort.

### **NIGHT-TIME OINTMENT**

Long-lasting Night-time Relief

### **Alcon®**

STERILE 3.5 g (0.12 fl oz)

NDC 0078-0473-97

Night-time PM  
Dry Eye Relief

# GenTeal®

LUBRICANT EYE OINTMENT

GenTeal® Night-time PM ointment provides long-lasting relief for night-time comfort.

## NIGHT-TIME OINTMENT

Long-lasting Night-time Relief

### Alcon®

STERILE 3.5 g (0.12 fl oz)

GenTeal®  
LUBRICANT EYE OINTMENT



550



TAMPER EVIDENT: For your protection, use only if cap and necking are intact at time of purchase.

Manufactured for:  
Alcon Laboratories, Inc.,  
a Novartis company  
6201 South Freeway  
Fort Worth TX, 76134 USA  
© Novartis 2009, 2011

9254400  
AND8134

LOT:  
EXP:

#### Questions?

In the U.S., call toll-free 1-866-393-6336. MedInfo@AlconLabs.com  
www.genteal.com  
Serious side effects associated with use of this product may be reported to this telephone number.

#### Other Information

Store between 15° - 25°C (59° - 77°F).

#### 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.

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

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

Stop use and ask a doctor if you experience any of the following:

When using this product do not touch tip of container to any surface. Replace cap after using.

#### Do not use

- if you are sensitive to any ingredient in this product

For external use only.

#### Warnings

- As a preservative against further irritation
- Temporarily relieves discomfort due to minor irritations of the eye or from exposure to wind or sun

#### Uses

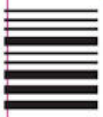
- Relieves dryness of the eye

#### Drug Facts

Active ingredients  
White petrolatum (85%)  
Mineral oil (15%)  
Lubricant

#### Purpose

550



# GENTEAL NIGHT-TIME PM

white petrolatum ointment

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:0078-0473
<b>Route of Administration</b>	OPHTHALMIC		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>Mineral Oil</b> (UNII: T5L8T28FGP) (Mineral Oil - UNII:T5L8T28FGP)	Mineral Oil	0.15 g in 1 g
<b>Petrolatum</b> (UNII: 4T6H12BN9U) (Petrolatum - UNII:4T6H12BN9U)	Petrolatum	0.85 g in 1 g

## Inactive Ingredients

Ingredient Name	Strength
<b>Lanolin</b> (UNII: 7EV65EAW6H)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0078-0473-97	1 in 1 CARTON	12/14/2009	11/29/2019
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	12/14/2009	11/29/2019

**Labeler** - Novartis Pharmaceutical Corporation (002147023)

## Establishment

Name	Address	ID/FEI	Business Operations
S.A. Alcon-Couvreur N.V.		370205429	manufacture(0078-0473)

Revised: 6/2019

Novartis Pharmaceutical Corporation