

**GENTEAL SEVERE- hypromellose gel**  
**Novartis Pharmaceuticals 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**

<b>Active ingredient</b>	<b>Purpose</b>
Hypromellose 0.3%.	Lubricant

**Uses**

- temporarily relieves discomfort due to minor irritations of the eye or to exposure to wind or sun
- as a protectant against further irritation or to relieve dryness of the eye

**Warnings**

**For external use only**

**Do not use**

- if gel changes color or becomes cloudy
- if you are sensitive to any ingredient in this product

**When using this product**

- do not touch tip of container to any surface
- replace cap after using

**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

**Keep out of reach of children.**

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

**Directions**

- put 1 or 2 drops in the affected eye(s) as needed

**Other information**

- store between 15° - 25°C (59° - 77°F)

**Inactive ingredients**

carbopol 980, phosphonic acid, purified water, sodium hydroxide, sodium perborate, and sorbitol

**Questions?**

In the U.S., call toll-free

**1-800-757-9195**

**(Mon-Fri 9AM-5PM CST)**

alcon.medinfo@alcon.com

**PRINCIPAL DISPLAY PANEL**

**Severe DRY EYE SYMPTOM RELIEF**

**GEL**

**GenTeal® Tears**

LUBRICANT EYE GEL

**GEL**

Delivers Long-lasting relief of dry eye symptoms

STERILE

10 g (0.34 FL OZ)

**Alcon®**



NDC 0078-0429-47

**Severe**  
**DRY EYE SYMPTOM RELIEF**  
**GEL**

**GenTeal® Tears**  
**LUBRICANT EYE GEL**

## GEL

Delivers Long-lasting relief of dry eye symptoms

*New Design*

STERILE

10 g (0.34 FL OZ)

Alcon®

Distributed by:

ALCON LABORATORIES, INC.

6201 South Freeway

Fort Worth, Texas 76134 USA

a Novartis Company

Country of Origin: Switzerland

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### Drug Facts

**Active ingredient Purpose**  
Hypromellose 0.3%.... Lubricant

#### Uses

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- temporarily relieves discomfort due to minor irritations of the eye or to exposure to wind or sun
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### Drug Facts (continued)

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NDC 0078-0429-47

**Severe GEL**  
DRY EYE  
SYMPTOM RELIEF



#### TAMPER EVIDENT:

For your protection, use only if pull tab is intact at time of purchase.

**GenTeal®**  
**Tears**  
LUBRICANT EYE GEL

**GEL**

Delivers Long-lasting  
relief of dry eye  
symptoms

*New  
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W25355200

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6201 South Freeway  
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Country of Origin: Switzerland  
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# GENTEAL SEVERE

hypromellose gel

## Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0078-0429
Route of Administration	OPHTHALMIC		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>Hypromellose 2910 (4000 Mpa.S)</b> (UNII: RN3152OP35) (Hypromellose 2910 (4000 Mpa.S) - UNII:RN3152OP35)	Hypromellose 2910 (4000 Mpa.S)	.003 g in 1 g

## Inactive Ingredients

Ingredient Name	Strength
<b>Sodium Perborate</b> (UNII: Y52BK1W96C)	
<b>Phosphonic Acid</b> (UNII: 35V6A8JW8E)	
<b>Water</b> (UNII: 059QF0KO0R)	
<b>Sodium Hydroxide</b> (UNII: 55X04QC32I)	
<b>Sorbitol</b> (UNII: 506T60A25R)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0078-0429-97	1 in 1 CARTON	09/14/2009	02/28/2015
1		3.5 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:0078-0429-47	1 in 1 CARTON	09/14/2009	
2		10 g in 1 TUBE; Type 0: Not a Combination Product		
3	NDC:0078-0429-57	2 in 1 CARTON	09/14/2009	
3		10 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	09/14/2009	

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

## Establishment

Name	Address	ID/FEI	Business Operations
Akorn AG		482198285	manufacture(0078-0429) , label(0078-0429) , pack(0078-0429)

## Establishment

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Excelvision		274234566	manufacture(0078-0429) , label(0078-0429) , pack(0078-0429)

## **Establishment**

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
SERVIPACK		571772875	label(0078-0429) , pack(0078-0429)

Revised: 7/2019

Novartis Pharmaceuticals Corporation