

GENTEAL TEARS SEVERE- hypromellose gel
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.

Drug Facts

<i>Active ingredient</i>	<i>Purpose</i>
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)

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

Distributed by:
ALCON LABORATORIES, INC.
Fort Worth, Texas 76134 USA
A Novartis Division

Lot/Exp

Alcon

25368102



GENTEAL TEARS SEVERE
 hypromellose gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0065-8064	
Route of Administration	OPHTHALMIC			
Active Ingredient/Active Moiety				
Ingredient Name		Basis of Strength	Strength	
Hypromellose 2910 (4000 Mpa.S) (UNII: RN3152OP35) (Hypromellose 2910 (4000 Mpa.S) - UNII:RN3152OP35)		Hypromellose 2910 (4000 Mpa.S)	.003 g in 1 g	
Inactive Ingredients				
Ingredient Name			Strength	
Sodium Perborate (UNII: Y52BK1W96C)				
Phosphonic Acid (UNII: 35V6A8JW8E)				
Water (UNII: 059QF0KO0R)				
Sodium Hydroxide (UNII: 55X04QC32I)				
Sorbitol (UNII: 506T60A25R)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0065-8064-01	1 in 1 CARTON	12/14/2019	
1		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		12/14/2019	

Labeler - Alcon Laboratories, Inc. (008018525)

Establishment			
Name	Address	ID/FEI	Business Operations
Excelvision		274234566	manufacture(0065-8064) , label(0065-8064) , pack(0065-8064)