# GENTEAL TEARS GEL DROPS- polyethylene glycol 400 and propylene glycol gel Alcon Laboratories, Inc.

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#### **Drug Facts**

Active Ingredients	Purpose
Polyethylene Glycol 400 0.4%	Lubricant
Propylene Glycol 0.3%	Lubricant

#### Uses

- for the temporary relief of burning and irritation due to dryness of the eye
- for use as a protectant against further irritation or to relieve dryness of the eye

## Warnings

#### For external use only

#### Do not use

- if this product 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 to avoid contamination
- replace cap after each use

#### **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

- shake well before using
- put 1 or 2 drops in the affected eye(s) as needed

## Other information

store at room temperature

## Inactive ingredients

Aminomethylpropanol, boric acid, edetate disodium, hydroxypropyl guar, POLYQUAD® (polyquaternium-1) 0.001% preservative, potassium chloride, sodium chloride, sorbitol and purified water. May contain hydrochloric acid and /or sodium hydroxide to adjust pH.

## **Questions?**

In the U.S. call 1-800-757-9195 alcon.medinfo@alcon.com www.genteal.com

Alcon Laboratories Inc. Fort Worth, TX 76134 USA

Made in the USA from domestic and imported materials

## 300038472-0920

## **TOP OF THE CARTON**

GenTeal<sup>®</sup> Tears

LUBRICANT EYE DROPS

Severe Day + Night DRY EYE SYMPTOM RELIEF GEL DROPS

## PRINCIPAL DISPLAY PANEL

Severe Day + Night

DRY EYE SYMPTOM RELIEF GEL DROPS

## GenTeaL<sup>®</sup> Tears

LUBRICANT EYE DROPS **GEL DROPS** Strength of a Gel, Convenience of a drop

#### STERILE

Alcon 8ml (0.3 FL OZ)

TAMPER EVIDENT:

For your protection, this bottle has a seal imprinted with Alcon around the neck. Do not use if seal is damaged or missing at time of purchase.

GENTEAL<sup>®</sup> TEARS Gel Drops contains two lubricants to deliver the relief of a gel with the comfort and convenience of a drop.



## **GENTEAL TEARS GEL DROPS**

polyethylene glycol 400 and propylene glycol gel

**Product Information** 

Item Code (Source)

Strength

4 mg

in 1 mL 3 mg

in 1 mL

 Route of Administration
 OPHTHALMIC

 Active Ingredient/Active Woiety
 Basis of Strength

 Ingredient Name
 Basis of Strength

 Polyethylene Glycol 400 (UNII: B697894SGQ) (Polyethylene Glycol 400 - UNII:B697894SGQ)
 Polyethylene Glycol 400 - 000 (UNII: B697894SGQ)

 Propylene Glycol (UNII: 6DC9Q16TV3) (Propylene Glycol - UNII:6DC9Q167V3)
 Propylene Glycol

#### **Inactive Ingredients**

Ingredient Name	Strength
Aminomethylpropanol (UNII: LU49E6626Q)	
Boric Acid (UNII: R57ZHV85D4)	
Edetate Disodium (UNII: 7FLD91C86K)	
Guaraprolose (3500 Mpa.S At 1%) (UNII: 3A1I7376TC)	
Polidronium Chloride (UNII: 6716Z5YR3G)	
Potassium Chloride (UNII: 660YQ98I10)	
Sodium Chloride (UNII: 451W47IQ8X)	
Sorbitol (UNII: 506T60A25R)	
Water (UNII: 059QF0KO0R)	
Hydrochloric Acid (UNII: QTT17582CB)	
Sodium Hydroxide (UNII: 55X04QC32I)	

#### Packaging

	#	ltem Code	Package Description	Marketing Start Date	Marketing End Date
	1		8 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product	02/04/2021	
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## **Marketing Information**

Marketing	Application Number or Monograph	Marketing Start	Marketing End
Category	Citation	Date	Date
OTC Monograph Drug	M018	02/04/2021	

Labeler - Alcon Laboratories, Inc. (008018525)

Establishment					
Name	Address	ID/FEI	<b>Business Operations</b>		
Alcon Research LLC		007672236	manufacture(0065-8067)		