GOODSENSE ARTIFICIAL TEARS- polyvinyl alcohol solution Proficient Rx LP

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

Uses

- temporary relieves burning and irritations due to dryness of the eye(s)
- protects against further irritation

Warnings

For external use only. Do not use if solution changes color or becomes cloudy or if you are sensitive to any ingredient in this product.

When using this product

- remove contact lenses before using
- 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 feel eye pain
- changes in vision occur
- redness or irritation of the eye gets worse or lasts more than 72 hours

If pregnant or breast-feeding,

ask a health professional before use.

Keep out of the reach of children.

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

Directions

- Instill 1 or 2 drops in the affected eye(s) as needed.
- Store at 15-25C (59-77F).
- Children under 6 years of age: Ask a doctor

Dosage and Administration

• Instill 1 or 2 drops in the affected eye(s) as needed.

Active Ingredient

Each mL contains: Polyvinyl Alcohol 5mg/ml and Povidone 6mg/ml - lubricant

Inactive Ingredients: Benzalkonium Chloride, Dextrose, Disodium Edetate, Potassium Chloride, Purified Water, Sodium Bicarbonate, Sodium Chloride, Sodium Citrate, Sodium Phosphate (Mono- and Dibasic)





NDC 63187-298-15

Lot #:00000 Exp. 00/00/00 SN# MASTER

Artificial Tears 15mL Lot #:00000 NDC 63187-298-15

Eye Drops SN#MASTER Exp:00/00/00

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Artificial Tears 15mL Lot #:00000 NDC 63187-298-15

Eye Drops SN#MASTER Exp:00/00/00

Relabeled By: Proficient Rx LP Thousand Oaks, CA 91320

Artificial Tears

15_mL

Eye Drops

Each mL contains: Polyvinyl Alcohol 5mg/mL Lubricant / Povidone 6mg/mL Lubricant

See Box. For external use only.

Product ID: RA029815

Dist. By: Geiss, Destin & Dunn, Inc. Peachtree City, GA 30269

Store at 20°-25°C (68°-77°F)

Keep medication out of the reach of children

Relabeled By:

Proficient Rx LP

Thousand Oaks, CA 91320

GOODSENSE ARTIFICIAL TEARS

polyvinyl alcohol solution

ı	Product	Information		
- 1				

Product Type HUMAN OTC DRUG Item Code (Source) NDC:63187-298(NDC:11716-0001)

Route of Administration OPHTHALMIC

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990) (POLYVINYL ALCOHOL - UNII:532B59J990)	POLYVINYL ALCOHOL, UNSPECIFIED	5 mg in 1 mL		
PO VIDO NE, UNSPECIFIED (UNII: FZ989GH94E) (PO VIDO NE - UNII: FZ989GH94E)	POVIDONE, UNSPECIFIED	6 mg in 1 mL		

Inactive Ingredients				
Ingredient Name	Strength			
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)				
DEXTROSE, UNSPECIFIED FORM (UNII: IY9 XDZ35W2)				
EDETATE DISO DIUM (UNII: 7FLD91C86K)				
POTASSIUM CHLORIDE (UNII: 660 YQ98 I10)				
WATER (UNII: 059QF0KO0R)				
SODIUM BICARBONATE (UNII: 8MDF5V39QO)				
SODIUM CHLORIDE (UNII: 451W47IQ8X)				
SO DIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)				
SO DIUM PHO SPHATE (UNII: SE337SVY37)				

Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:63187-298-15	1 in 1 CARTON	0 1/0 1/20 19		
1		15 mL in 1 BOTTLE; Type 0: Not a Combination Product			

Marketing Information					
Marketing Category Application Number or Monograph Cit		Marketing Start Date	Marketing End Date		
OTC monograph final	part349	07/22/2010			

Labeler - Proficient Rx LP (079196022)

Establishment			
Name	Address	ID/FEI	Business Operations
Proficient Rx LP		079502574	REPACK(63187-298), RELABEL(63187-298)

Revised: 1/2019 Proficient Rx LP