GOODSENSE LUBRICANT EYE- polyethylene glycol 400, and propylene glycol solution/ drops Geiss, Destin & Dunn, 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.

GoodSense Lubricant Eye Drops 30 ct. NBE Systane 5474 (2018)

Active ingredients Purposes

Polyethylene glycol 400 0.4%.....Eye lubricant

Propylene glycol 0.3%.....Eye lubricant

Use

• for the temporary relief of burning and irritation due to dryness of the eye

Warnings

For external use only

Do not use

- if the solution 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
- do not reuse
- once opened, discard
- remove contact lenses before using

Stop use and ask a doctor if

- you feel eye pain
- changes in vision occur
- redness or irritation of the eve(s) lasts
- condition worsens or lasts more than 72 hours

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center (1-800-222-1222) right away.

Directions

- to open, twist and pull tab to remove
- instill 1 or 2 drops in the affected eye(s) as needed
- children under 6 years of age: ask a doctor

Other information

- store at room temperature 20-25°C (68-77°F)
- protect from light

Inactive ingredients

aminomethylpropanol, boric acid, hydrochlorid acid, hydroxyethyl cellulose, potassium chloride, purified water, sodium chloride, sodium hydroxide, sorbitol

Distributed by:

Geiss, Destin & Dunn, Inc. Peachtree City, GA 30269 www.valuelabels.com Made in South Korea



GOODSENSE LUBRICANT EYE

polyethylene glycol 400, and propylene glycol solution/ drops

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50804-665
Route of Administration	OPHTHALMIC		

	Active Ingredient/Active Moiety		
ı	Ingredient Name	Basis of Strength	Strength

POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ) (POLYETHYLENE GLYCOLS -	POLYETHYLENE GLYCOL	4 mg
UNII:3WJQ0SDW1A)	400	in 1 mL
PROPYLENE GLYCOL (UNII: 6 DC9 Q167V3) (PROPYLENE GLYCOL - UNII:6 DC9 Q167V3)	PROPYLENE GLYCOL	3 mg in 1 mL

Inactive Ingredients		
Ingredient Name	Strength	
SO DIUM HYDRO XIDE (UNII: 55X04QC32I)		
SORBITOL (UNII: 506T60A25R)		
SODIUM CHLORIDE (UNII: 451W47IQ8X)		
AMINO METHYLPRO PANOL (UNII: LU49E6626Q)		
HYDRO CHLO RIC ACID (UNII: QTT17582CB)		
BORIC ACID (UNII: R57ZHV85D4)		
POTASSIUM CHLORIDE (UNII: 660 YQ98 I10)		
WATER (UNII: 059QF0KO0R)		

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:50804-665-30	30 in 1 CARTON	04/18/2018	
1	0.4 mL in 1 VIAL; 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	0 4/17/20 18		

Labeler - Geiss, Destin & Dunn, Inc (076059836)

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