SYSTANE ULTRA SINGLE VIALS- polyethylene glycol and propylene glycol solution/ drops
United Exchange Corp.

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.

Systane Ultra Single Eye Drops 0.4 ml 16843ZZ (2018)

Active ingredients Purpose

Polyethylene glycol 400 0.4%.....Lubricant

Propylene glycol 0.3%.....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 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
- do not reuse
- once opened, discard

Stop use and ask a doctor if

- you feel eye pain
- changes in vision occur
- redness or irritation of the eye(s) gets worse, persists or last more than 72 hours

Keep out of 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.

Other information

- store at room temperature

Inactive ingredients

aminomethylpropanol, boric acid, hydrochloric acid, hydroxyethyl cellulose, potassium chloride, sodium hydroxide, sorbitol, water for injection

Made in South Korea

SYSTANE ULTRA SINGLE VIALS

polyethylene glycol and propylene glycol solution/ drops

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:65923-843
Route of Administration	OPHTHALMIC		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
PROPYLENE GLYCOL (UNII: 6DC9Q167V3) (PROPYLENE GLYCOL - UNII:6DC9Q167V3)	PROPYLENE GLYCOL	3 mg in 1 mL
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ) (POLYETHYLENE GLYCOLS - UNII:3WJQ0SDW1A)	POLYETHYLENE GLYCOL 400	4 mg in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
BORIC ACID (UNII: R57ZHV85D4)	
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	
WATER (UNII: 059QF0KO0R)	
HYDROXYETHYL CELLULOSE (1800 MPA.S AT 2%) (UNII: 6OX6A5C7B6)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SORBITOL (UNII: 506T60A25R)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
HYDROCHLORIC ACID (UNII: QTT17582CB)	
POTASSIUM CHLORIDE (UNII: 660YQ98I10)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65923-843-04	0.4 mL in 1 VIAL; Type 0: Not a Combination Product	01/02/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part349	01/02/2017	

Labeler - United Exchange Corp. (840130579)

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