STYE- polyvinyl alcohol and povidone solution/ drops Medtech Products 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.

Stye Eye Drops 63029-324

Drug Facts

Active ingredients

Polyvinyl alcohol 0.5% Povidone 0.6%

Purpose

Lubricant Lubricant

Uses

For temporary relief of discomfort due to minor irritations including: burning, stinging, itching.

Warnings

for external use only

Do not use

if solution changes color or becomes cloudy

When using this product

- to avoid contamination, do not touch tip to any surface
- replace cap after using

Stop use and ask a doctor if

- you experience eye pain
- you experience changes in vision
- you experience continued redness or irritation of the eye
- the 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 (1-800-222-1222) right away

Directions

instill 1 to 2 drops in the affected eye(s) as needed

Other information

- store at room temperature
- remove contact lenses before using

Inactive ingredients

benzalkonium chloride, dextrose, dibasic sodium phosphate, edetate disodium, monobasic sodium phosphate, potassium chloride, purified water, sodium bicarbonate, sodium chloride, sodium citrate

Questions?

1-800-344-7239

PRINCIPAL DISPLAY PANEL

Stve ™

LUBRICANT EYE DROPS

STERILE 0.5 fl oz (15 mL)



STYE

polyvinyl alcohol and povidone solution/ drops

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63029-324

Route of Administration OPHTHALMIC

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990) (POLYVINYL ALCOHOL, UNSPECIFIED - UNII:532B59J990)	POLYVINYL ALCOHOL, UNS PECIFIED	5 mg in 1 mL		
POVIDONE (UNII: FZ 989GH94E) (POVIDONE - UNII: FZ 989GH94E)	POVIDONE	6 mg in 1 mL		

Inactive Ingredients			
Ingredient Name	Strength		
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)			
DEXTROSE (UNII: IY9XDZ35W2)			
SODIUM PHOSPHATE, DIBASIC (UNII: GR686LBA74)			
EDETATE DISODIUM (UNII: 7FLD91C86K)			
SODIUM PHOSPHATE, MONOBASIC (UNII: 3980JIH2SW)			
POTASSIUM CHLORIDE (UNII: 660YQ98I10)			
SODIUM BICARBONATE (UNII: 8MDF5V39QO)			
SODIUM CHLORIDE (UNII: 451W47IQ8X)			
SODIUM CITRATE (UNII: 1Q73Q2JULR)			

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Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63029- 324-15	1 in 1 BOTTLE	12/01/2021	
1		15 mL in 1 BOTTLE, DROPPER; 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	12/01/2021	

Labeler - Medtech Products Inc. (122715688)

Revised: 10/2021 Medtech Products Inc.