ICS3 BLUE HEALTHCARE HAND ANTISEPTIC- alcohol liquid Biocentris Pharmaceuticals, LLC

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.

Biocentris ICS3 Blue Healthcare Hand Antiseptic (70% Alcohol)

Drug Facts

Active ingredient

Alcohol 70% (v/v)

Purpose

Antiseptic

Uses

- To decrease bacteria on the skin after changing diapers, after assisting ill persons or before contact with a person under medical care or treatment.
- Recommended for repeated use.

Warnings

For external use only. Flammable. Keep away from fire or flame.

When using this product keep out of eyes. In case of eye contact, flush eyes with water.

Stop use and ask a doctor if irritation or redness develop or if condition persists for more than 72 hours.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center immediately.

Directions

- Apply liberally to hands to cover all surfaces.
- Rub hands together until dry.
- Supervise children under 6 years old.
- Not recommended for infants.

Inactive ingredients Benzalkonium Chloride, Chlorhexidine Gluconate, Isopropyl Alcohol, PEG-10 Dimethicone, Polyethylene Oxide 600000, Phenoxyethanol, Polyquaternium 10, Water

Manufactured for:

biocentris PHARMACEUTICALS

24 Executive Parkway, Ringwood, NJ 07456

888-497-4375

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ICS3®

INFECTION CONTROL SYSTEM 3

HEALTHCARE HAND ANTISEPTIC

ALCOHOL FOAM

16.9 fl. oz. (500 mL)



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BIO-5076-FL500

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Rev. 1.02

ICS3 BLUE HEALTHCARE HAND ANTISEPTIC

alcohol liquid

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:81232-150

Route of Administration TOPICAL

Active Ingredient/Active Moiety

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Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	70 mL in 100 mL

Inactive Ingredients			
Ingredient Name	Strength		
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)			
CHLORHEXIDINE GLUCONATE (UNII: MOR84MUD8E)			
ISOPROPYL ALCOHOL (UNII: ND2M416302)			
PEG-10 DIMETHICONE (600 CST) (UNII: 8PR7V1SVM0)			
POLYETHYLENE OXIDE 600000 (UNII: 2126FD486L)			
PHENOXYETHANOL (UNII: HIE492ZZ3T)			
POLYQUATERNIUM-10 (30000 MPA.S AT 2%) (UNII: C7RDC8Y4JS)			
WATER (UNII: 059QF0KO0R)			

P	Packaging						
#	Item Code	Package Description	Marketing Start Date	Marketing End Date			
1	NDC:81232- 150-10	1000 mL in 1 POUCH; Type 0: Not a Combination Product	04/26/2022				
2	NDC:81232- 150-17	500 mL in 1 POUCH; Type 0: Not a Combination Product	04/26/2022				
3	NDC:81232- 150-43	1000 mL in 1 CARTRIDGE; Type 0: Not a Combination Product	04/26/2022				
4	NDC:81232- 150-18	532 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/26/2022				

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333E	04/26/2022		

Labeler - Biocentris Pharmaceuticals, LLC (015882747)

Revised: 4/2022 Biocentris Pharmaceuticals, LLC