PREVENTMD EXTRACLEAN HYDRATING HAND SANITIZER- alcohol gel Iontera, 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.

PREVENTMD EXTRACLEAN HYDRATING HAND SANITIZER

Drug Facts

Active ingredient

Alcohol 63% v/v

Purpose

Antiseptic

Uses

Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.

Warnings

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

Do not use

- in children less than 2 months of age.
- on open skin wounds.

When using this product

keep out of eyes, ears and mouth. In case of contact with eyes, rinse eyes thoroughly with water.

Stop use and ask a doctor if

irritation or rash occurs. These may be signs of a serious condition.

Keep out of reach of children.

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

Directions

- Place enough product on hands to cover all surfaces. Rub hands together until dry.
- Supervise children under 6 years of age when using this product to avoid swallowing.

Other information

- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F).

Inactive ingredients

Water, Butylene Glycol, Glycerin, Sodium Hyaluronate, Aloe Barbadensis Leaf Juice, Hydrolyzed Collagen, Carbomer, 1,2-Hexanediol, Ethylhexylglycerin, Triethanolamine, Phenoxyethanol, Fragrance

Company Information

DIST. BY/PAR RARE BEAUTY BRANDS, INC. 83 MORSE ST. NORWOOD MA, 02062 ALL RIGHTS RESERVED. DESIGNED IN THE USA. MADE IN KOREA.

Product Packaging - 50 mL

preventMD

EXTRACLEAN

hydrating

hand sanitizer

contains 63% alcohol

50 mL 1.7 Fl. Oz.





PREVENTMD EXTRACLEAN HYDRATING HAND SANITIZER alcohol gel Product Information Product Type HUMAN OTC DRUG Item Code (Source) Route of Administration TOPICAL

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	63 mL in 100 mL	

Inactive Ingredients				
Ingredient Name	Strength			
PHENO XYETHANOL (UNII: HIE492ZZ3T)				
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)				
TROLAMINE (UNII: 9O3K93S3TK)				
1,2-HEXANEDIO L (UNII: TR0 46 Y3K1G)				
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)				
CARBOMER HOMO POLYMER, UNSPECIFIED TYPE (UNII: 0 A5MM307FC)				
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)				
GLYCERIN (UNII: PDC6A3C0OX)				
HYALURO NATE SO DIUM (UNII: YSE9 PPT4TH)				
WATER (UNII: 059QF0KO0R)				

P	Packaging						
#	Item Code	Package Description	Marketing Start Date	Marketing End Date			
1	NDC:72204-003-01	50 mL in 1 POUCH; Type 0: Not a Combination Product	04/22/2020				
2	NDC:72204-003-02	23 mL in 1 POUCH; Type 0: Not a Combination Product	04/22/2020				
3	NDC:72204-003-03	50 in 1 BOX	04/22/2020				
3		3.5 mL in 1 PACKET; Type 0: Not a Combination Product					
4	NDC:72204-003-04	30 in 1 BOX	04/22/2020				
4		3 mL in 1 PACKET; Type 0: Not a Combination Product					

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC monograph not final	part333A	04/22/2020			

Labeler - Iontera, Inc (004818058)

Revised: 4/2020 Iontera, Inc