FRIGELL HAND SANITIZER- alcohol gel
Lenomex, S.A. de C.V.

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.

Frigell Hand Sanitizer

Drug Facts

Active Ingredient:

Ethyl Alcohol at 75%

Purpose:

Antiseptic

Uses:

Hand Sanitizer to help reduce bacteria and germs on skin. For use when soap and water not available.

Warnings:

Flammable. Keep away from fire or open flame and sources of heat or flame.

For external use only.

Do not use:

In children less than 2 months of age. On open skin wounds.

When using this product:

Keep out of eyes. Do not use in or near the eyes, ears and mouth. In case of contact with eyes, rinse eyes thoroughly

Stop use and ask doctor:

If irritation or rash appears or occurs. These may be a 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:

Apply a small amount of Frigell in your hand palms and rub hands together and between fingers until dry.

Supervise children under 6 years of age when using this product.

Other Information:

Store below 110°F (43°C). Avoid freezing. May discolor certain fabrics or surfaces.

Inactive Ingredients:

Water (Aqua), Carbomer, Glycerine, Triethanolamine, Benzalkonium Chloride.

Package Labeling:

FRIGELL HAND SANITIZER

alcohol gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:79251-000
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	0.75 mL in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
WATER (UNII: 059QF0KO0R)	
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
GLYCERIN (UNII: PDC6A3C0OX)	
TROLAMINE (UNII: 9O3K93S3TK)	

BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79251-000-03	60 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/09/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	07/09/2020	

Labeler - Lenomex, S.A. de C.V. (810463562)

Revised: 7/2020 Lenomex, S.A. de C.V.