NORTHMED HAND SANITIZER- benzalkonium chloride gel Northmed SIA

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.

Active Ingredient

Benzalkonium Chloride 0.2%

Purpose

Antiseptic

Use

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.

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

- Apply a small amount of gel to hands and massage. Wait for it to dry. The exposure time is 15-0 seconds.
- Supervise children under 6 years of age when using this product to avoid swallowing.

Other information

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

Inactive ingredients

Water, Glycerine, Panthenol, Aloe vera, Hydroxyethyl cellulose, Tetrasodium Glutamate Diacetate, Fragrance, Linalool, Citronellol

Package Label - Principal Display Panel

2 mL



50 mL





www.northmedusa.com

250ml/8.45 fl.oz.



ALCOHOL FREE

HAND SANITIZER









GEL



Drug Facts Active Ingredient benzakonium chloride 0.20% Purpose Use(s) Hand sanitizer to help reduce bacteria that potentially can couse disease. For use when soap and water are not available. 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, rirse eyes thoroughly with water Stop use and aska doctor if ■ irritation and rash occurs. These may be signs of serious condition. Keep out of reach of children. If swallowed, get medical help or contact Poison Control Center right away. ■apply a small amount of gel to the hands and massage. Wait for it to dry. The exposure time is 15-30 seconds. ■ Supervise children under 6 years of age when using this product to avoid swallowing. Other Information Store between 59-86F (15-30C) ■Avoid freezing and excessive heat above 104F (40C)

Inactive Ingredients: Water, Glycerine, Panthenol, Albe Vera, Hydroxyethyl Cellulose, Tetrasodium Glutamate Diocetate, Fragrance, Linabol, Ctronellol

Extremely Gentle Disinfectant Gel for Hand and Skin Protection.

D-panthenol and Aloe Vera provide natural hydration and protect the skin from dryness by preventing cracking. Its double biocide properties ensure high efficiency against viruses, bacteria, fungi. It dries in a few seconds, leaving a pleasant feeling of softness and freshness.











1L/0,26 gal







ALCOHOL FREE

HAND SANITIZER













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Inactive Ingredients Water, Glycerine, Panthenol, Aloe Vera, Hydroxyethyl Cellulose, Tetrasodium Glutamate Diacetate, Fagrance, Linalcol, Citronellol

4L/1,06 gal





Northmed Inc. Atlanta, GA, 30327, USA, www.northmedusa.com info@northmedusa.com, Made In EU





NORTHMED HAND SANITIZER

benzalkonium chloride gel

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:78522-010

Route of Administration TOPICAL

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
BENZALKO NIUM CHLO RIDE (UNII: F5UM2KM3W7) (BENZALKO NIUM - UNII:7N6 JUD5X6 Y)	BENZALKONIUM CHLORIDE	2 mg in 1 mL		

Inactive Ingredients	
Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6 A3C0 OX)	
PANTHENOL (UNII: WV9CM0O67Z)	
HYDROXYETHYL CELLULOSE (140 MPA.S AT 5%) (UNII: 8136 Y38 GY5)	
TETRASODIUM GLUTAMATE DIACETATE (UNII: 5EHL50 I4MY)	
LINALOOL, (+/-)- (UNII: D81QY6188E)	
.BETACITRONELLOL, (+/-)- (UNII: 5650K72VNF)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78522-010-01	24 in 1 PACKAGE	07/22/2020	
1		2 mL in 1 POUCH; Type 0: Not a Combination Product		
2	NDC:78522-010-02	50 mL in 1 TUBE; Type 0: Not a Combination Product	07/22/2020	
3	NDC:78522-010-03	250 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/22/2020	
4	NDC:78522-010-04	1000 mL in 1 BAG; Type 0: Not a Combination Product	07/22/2020	
5	NDC:78522-010-05	4000 mL in 1 BAG; Type 0: Not a Combination Product	07/22/2020	

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC monograph not final	part333A	07/22/2020			

Labeler - Northmed SIA (662588132)

Establishment			
Name	Address	ID/FEI	Business Operations
Northmed SIA		662588132	manufacture (78522-010)

Revised: 7/2020 Northmed SIA