HAND SANITIZER- benzalkonium chloride gel
Northmed

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.

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gel for kids, 80ml

Active ingredient

benzalkonium chloride 0.20%

Purpose

Antiseptic

Use(s)

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

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

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

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

Directions

Directions. 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.

Storage.

Store between 41-80F (5-27C). Avoid freezing and excessive heat above 104F (40C).

Inactive Ingredients

Inactive Ingredients.Water. glycerin, panthenol, aloe vera, hydroxyethyl cellulose, tetrasodium glutamate diacetate, fragrance, chamomile extract, birch leaf extract, elderberry extract.

Labels (80ml)

HAND SANITIZER

benzalkonium chloride gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:78522-101
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	2 mg in 80 mL

Inactive Ingredients

Ingredient Name	Strength
FRAGRANCE FLORAL ORC0902236 (UNII: R66Z4YW3X0)	
WATER (UNII: 059QF0KO0R)	
TETRASODIUM GLUTAMATE DIACETATE (UNII: 5EHL50I4MY)	
GLYCERIN (UNII: PDC6A3C0OX)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
HYDROXYETHYL CELLULOSE, UNSPECIFIED (UNII: T4V6TWG28D)	
BIRCH TRITERPENES (UNII: BX09B0RQR0)	
PANTHENOL (UNII: WV9CM0O67Z)	
CHAMOMILE FLOWER OIL (UNII: 60F80Z61A9)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78522-101-00	80 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/15/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	03/15/2021	

Labeler - Northmed (662588132)

Establishment

Name	Address	ID/FEI	Business Operations
Northmed		662588132	manufacture(78522-101) , pack(78522-101) , label(78522-101)

Revised: 3/2021 Northmed