

## **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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### **Active Ingredient**

Benzalkonium Chloride, .2%. Purpose: Antiseptic

### **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.

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### **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.

**Other information**

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

**Inactive ingredients**

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

**Package Label - Principal Display Panel**

140



ALCOHOL FREE  
**HAND  
SANITIZER  
GEL**

**KILLS UP TO  
99,9%  
VIRUSES  
& BACTERIA**



**PREMIUM**  
+D-Panthenol & Aloe vera



<b>Drug Facts</b>	
<b>Active Ingredient</b> benzalkonium chloride 0.20%	<b>Purpose</b> Antiseptic
<b>Use(s)</b> Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.	
<b>Warnings</b> For external use only.	
<b>Do not use</b> ■ in children less than 2 months of age ■ on open skin wounds	
<b>When using this product</b> ■ Keep out of eyes, ears and mouth. In case of contact with eyes, rinse eyes thoroughly with water	
<b>Stop use and ask a doctor if</b> ■ irritation and rash occurs. These may be signs of serious condition.	
<b>Keep out of reach of children.</b> If swallowed, get medical help or contact Poison Control Center right away.	
<b>Directions</b> ■ 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.	
<b>Other Information</b> ■ Store between 59-86F (15-30C) ■ Avoid freezing and excessive heat above 104F (40C)	
<b>Inactive Ingredients</b> Water, Glycerine, Panthenol, Aloe Vera, Hydroxyethyl Cellulose, Tetrasodium Glutamate Diacetate, Fragrance, Chamomile Extract, Birch Leaves Extract, Elderberry Extract	

**HAND SANITIZER GEL  
FOR KIDS**  
Extremely gentle disinfectant gel  
for hand and skin protection



D-panthenol and Aloe Vera Gel 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.

Specially Manufactured for Northmed Inc.  
Atlanta, GA, 30327, USA,

**Made in EU**  
info@northmed.eu  
www.northmed.eu

4751036340221



U2221



**1.05 Gal/4L**

Batch No. / Best before:  
See on the packaging

4L NDC: 78522-101-01

**HAND SANITIZER**

benzalkonium chloride gel

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:78522-103
<b>Route of Administration</b>	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
<b>BENZALKONIUM CHLORIDE</b> (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII: 7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	2 mg in 4 L

Inactive Ingredients	
Ingredient Name	Strength
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>FRAGRANCE FLORAL ORC0902236</b> (UNII: R66Z4YW3X0)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>CHAMOMILE FLOWER OIL</b> (UNII: 60F80Z61A9)	
<b>HYDROXYETHYL CELLULOSE, UNSPECIFIED</b> (UNII: T4V6TWG28D)	
<b>PANTHENOL</b> (UNII: WW9CM0067Z)	
<b>TETRASODIUM GLUTAMATE DIACETATE</b> (UNII: 5EHL50I4MY)	
<b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)	
<b>BIRCH TRITERPENES</b> (UNII: BX09B0RQR0)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78522-103-00	4 L in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	03/30/2020	

**Labeler** - Northmed (662588132)

Establishment			
Name	Address	ID/FEI	Business Operations
Northmed		662588132	manufacture(78522-103) , pack(78522-103) , label(78522-103)

Revised: 3/2021

Northmed