

## **HAND SANITIZER- ethyl alcohol gel**

### **Hemani International**

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The hand sanitizer is manufactured using only the following ingredients in the preparation of the product (percentage in final product formulation):

- a. Alcohol (ethanol) (USP or Food Chemical Codex (FCC) grade) (80%, volume/volume (v/v))
- b. Sterile distilled water or boiled cold water.
- c. Glycerol (5% v/v).
- d. Carbomer Copolymer Type A (Allyl Pentaerythritol Crosslinked)(1.5% v/v).
- e. Propylene Glycol (1% v/v).
- f. Fragrance (Dimethyl Anthranilate) (0.5% v/v).
- g. Triethanolamine (0.15% v/v).
- h. Dexpanthenol (Panthenol) (0.10% v/v).
  - i. Aloe Barbadensis Leaf Juice Powder (0.05% v/v).
  - j. Beads (Mannitol, Microcrystalline Cellulose, Hydroxypropyl Methylcellulose, Pigment Green 7 (CI 74260) (0.02% v/v).
- k. Blue 1 (CI 42090) (0.005% v/v).

The firm does not add other active or inactive ingredients besides listed above.

### **Active Ingredient(s)**

Ethyl Alcohol 80% v/v. Purpose: Antiseptic

### **Purpose**

Antiseptic, Hand Sanitizer

### **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. 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.

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 (aqua), glycerin (glycerol), Carbomer Copolymer Type A (Allyl Pentaerythritol Crosslinked), propylene glycol, Fragrance (Dimethyl Anthranilate), Triethanolamine, Dexpanthenol (Panthenol), Aloe Barbadosensis Leaf Juice Powder, Beads [(Mannitol, Microcrystalline Cellulose, Hydroxypropyl Methylcellulose, Pigment Green 7 (CI 74260)], Blue 1 (CI 42090)

### **Package Label - Principal Display Panel**

50 mL NDC: 75360-1125-1

65 mL NDC: 75360-1125-2

100 mL NDC: 75360-1125-3

250 mL NDC: 75360-1125-4

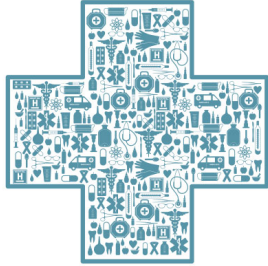
1 L NDC: 75360-1125-5

500 mL NDC: 75360-1125-6



Live Natural

# ANTISEPTIC HAND SANITIZER



kills 99.99% of germs\*

WITH NATURAL BEADS  
FOR SMOOTH & SOFT SKIN

50 mL (1.69 fl oz) e

## Drug Facts

Active Ingredient	Purpose
Ethyl Alcohol 80%.....	Antiseptic

**Uses** ■ to help reduce bacteria that potentially can cause disease.  
■ For use when soap and water are not available.

**Warning** ■ 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** ■ Avoid contact with mouth, ears and eyes.  
■ In case of contact, flush eyes with water.

**Stop use and ask a doctor if** ■ irritation or rash occurs. These may be signs of a serious condition.

**Keep out of the 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 (Aqua), Glycerin (Glycerol), Carbomer Copolymer Type A (Allyl Pentaerythritol Crosslinked), Propylene Glycol, Fragrance (Dimethyl Anthranilate), Triethanolamine, Dexpanthenol (Panthenol), Aloe Barbadensis Leaf Juice Powder, Beads [Mannitol, Microcrystalline Cellulose, Hydroxypropyl Methylcellulose, Pigment Green 7 (CI 74260)], Blue 1 (CI 42090).

Easy to carry & refresh your hands on the go.

Made in Pakistan

\* Effectively kills 99.99% of germs & bacteria in as little as 15 seconds.

NDC: 75360-1125-1



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Hemani International KEPZ, Karachi, Pakistan

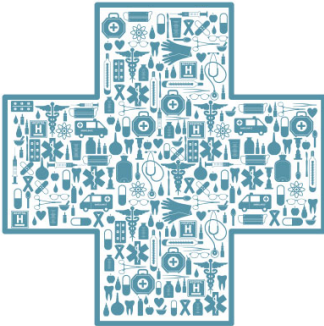
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www.hemaniherbals.com. info@hemanitrading.ae.



Live Natural

# ANTISEPTIC HAND SANITIZER



kills 99.99% of germs\*  
**WITH NATURAL BEADS**  
FOR SMOOTH & SOFT SKIN  
**65 mL (2.19 fl oz) e**

<b>Drug Facts</b>	
<b>Active Ingredient</b>	<b>Purpose</b>
Ethyl Alcohol 80%.....	Antiseptic
<b>Uses</b> ■ to help reduce bacteria that potentially can cause disease. ■ For use when soap and water are not available.	
<b>Warning</b> ■ For external use only ■ Flammable. ■ Keep away from heat or flame	
<b>Do Not Use</b> ■ in children less than 2 months of age ■ on open skin wounds	
<b>When using this product</b> ■ Avoid contact with mouth, ears and eyes. ■ In case of contact, flush eyes with water.	
<b>Stop use and ask a doctor if</b> ■ irritation or rash occurs. These may be signs of a serious condition.	
<b>Keep out of the reach of children</b> If swallowed, get medical help or contact a Poison Control Center right away.	
<b>Directions</b> ■ 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.	
<b>Other Information</b> ■ Store between 15-30C (59-86F) ■ Avoid freezing and excessive heat above 40C (104F)	
<b>Inactive Ingredients</b> ■ Water (Aqua), Glycerin (Glycerol), Carbomer Copolymer Type A (Allyl Pentaerythritol Crosslinked), Propylene Glycol, Fragrance (Dimethyl Anthranilate), Triethanolamine, Dexpanthenol (Panthenol), Aloe Barbadensis Leaf Juice Powder, Beads [Mannitol, Microcrystalline Cellulose, Hydroxypropyl Methylcellulose, Pigment Green 7 (CI 74260)], Blue 1 (CI 42090).	

**Easy to carry & refresh your hands on the go.**

\* Effectively kills 99.99% of germs & bacteria in as little as 15 seconds.



Made in Pakistan

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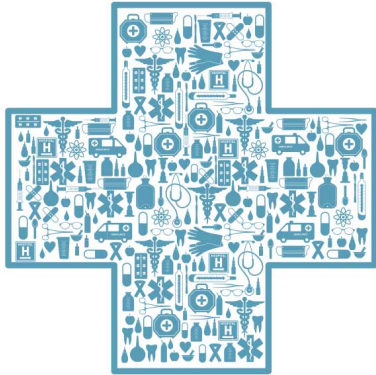
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Live Natural

# ANTISEPTIC HAND SANITIZER



kills 99.99% of germs\*

WITH NATURAL BEADS

FOR SMOOTH & SOFT SKIN

100 mL (3.38 fl oz) e

## Drug Facts

Active Ingredient	Purpose
Ethyl Alcohol 80%.....	Antiseptic

**Uses** ■ to help reduce bacteria that potentially can cause disease.  
■ For use when soap and water are not available.

**Warning** ■ 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** ■ Avoid contact with mouth, ears and eyes.  
■ In case of contact, flush eyes with water.

**Stop use and ask a doctor if** ■ irritation or rash occurs. These may be signs of a serious condition.

**Keep out of the 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 (Aqua), Glycerin (Glycerol), Carbomer Copolymer Type A (Allyl Pentaerythritol Crosslinked), Propylene Glycol, Fragrance (Dimethyl Antranilate), Triethanolamine, Dexpanthenol (Panthenol), Aloe Barbadensis Leaf Juice Powder, Beads [Mannitol, Microcrystalline Cellulose, Hydroxypropyl Methylcellulose, Pigment Green 7 (CI 74260)], Blue 1 (CI 42090).

Easy to carry & refresh your hands on the go.

\*Effectively kills 99.99% of germs & bacteria in as little as 15 seconds.



Made in Pakistan

NDC: 75360-1125-3



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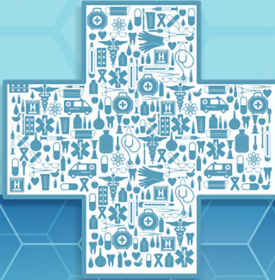
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**HEMANI**

*Live Natural*

# ANTISEPTIC HAND SANITIZER



kills 99.99% of germs\*

WITH NATURAL BEADS

FOR SMOOTH & SOFT SKIN

250 mL (8.45 fl oz) e

**Refresh your  
hands on the go!**

\*Effectively kills 99.99% of germs  
and bacteria in as little as 15 seconds.

### **Drug Facts**

Active Ingredient	Purpose
Ethyl Alcohol 80%.....	Antiseptic

**Uses** ■ to help reduce bacteria that potentially can cause disease.  
■ For use when soap and water are not available.

**Warning** ■ 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** ■ Avoid contact with mouth, ears and eyes.  
■ In case of contact, flush eyes with water.

**Stop use and ask a doctor if** ■ irritation or rash occurs. These may be signs of a serious condition.

**Keep out of the 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 (Aqua), Glycerin (Glycerol), Carbomer Copolymer Type A (Allyl Pentaerythritol Crosslinked), Propylene Glycol, Fragrance (Dimethyl Antranilate), Triethanolamine, Dexpantenol (Panthenol), Aloe Barbadosis Leaf Juice Powder, Beads [Manritol, Microcrystalline Cellulose, Hydroxypropyl Methylcellulose, Pigment Green 7 (CI 74260)], Blue 1 (CI 42090).

Made in Pakistan  
NDC: 75360-1125-4



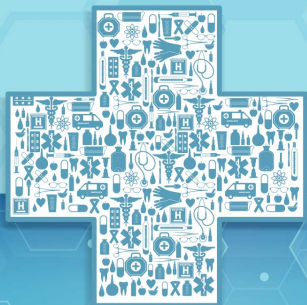
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**HEMANI**

*Live Natural*

# ANTISEPTIC HAND SANITIZER



kills 99.99% of germs\*  
WITH NATURAL BEADS  
FOR SMOOTH & SOFT SKIN

1 L (33.8 fl oz) e

## Drug Facts

Active Ingredient	Purpose
Ethyl Alcohol 80%.....	Antiseptic

**Uses** ■ to help reduce bacteria that potentially can cause disease.  
■ For use when soap and water are not available.

**Warning** ■ 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** ■ Avoid contact with mouth, ears and eyes.  
■ In case of contact, flush eyes with water.

**Stop use and ask a doctor if** ■ irritation or rash occurs. These may be signs of a serious condition.

**Keep out of the 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.

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### Hand Sanitizer Refiller. Value Size.

\*Effectively kills 99.99% of germs & bacteria in as little as 15 seconds.



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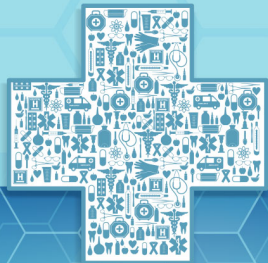
Made in Pakistan  
NDC: 75360-1125-6



**HEMANI**

*Live Natural*

# ANTISEPTIC HAND SANITIZER



kills 99.99% of germs\*  
WITH NATURAL BEADS  
FOR SMOOTH & SOFT SKIN

500 mL (16.9 fl oz) e

### Refresh your hands on the go!

\*Effectively kills 99.99% of germs  
and bacteria in as little as 15 seconds.

## Drug Facts

Active Ingredient	Purpose
Ethyl Alcohol 80%.....	Antiseptic

**Uses** ■ to help reduce bacteria that potentially can cause disease.  
■ For use when soap and water are not available.

**Warning** ■ 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

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**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.

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**Inactive Ingredients** ■ Water (Aqua), Glycerin (Glycerol), Carbomer Copolymer Type A (Allyl Pentaerythritol Crosslinked), Propylene Glycol, Fragrance (Dimethyl Anthranilate), Triethanolamine, Dexpanthenol (Panthenol), Aloe Barbadensis Leaf Juice Powder, Beads (Mannitol, Microcrystalline Cellulose, Hydroxypropyl Methylcellulose, Pigment Green 7 (CI 74260), Blue 1 (CI 42090).

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NDC: 75360-1125-6

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# HAND SANITIZER

ethyl alcohol gel

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:75360-1125
<b>Route of Administration</b>	TOPICAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	80 mL in 100 mL

## Inactive Ingredients

Ingredient Name	Strength
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	0.005 mL in 100 mL
TROLAMINE (UNII: 9O3K93S3TK)	0.15 mL in 100 mL
ALOE VERA LEAF (UNII: ZY81Z83H0X)	0.05 mL in 100 mL
DIMETHYL ANTHRANILATE (UNII: 5Z37T562P9)	0.5 mL in 100 mL
MANNITOL (UNII: 3OWL53L36A)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
PIGMENT GREEN 7 (UNII: BPO9294G4W)	
DEXPANTHENOL (UNII: 1O6C93RI7Z)	0.1 mL in 100 mL
CARBOMER COPOLYMER TYPE A (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 71DD5V995L)	1.5 mL in 100 mL
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	1 mL in 100 mL
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
GLYCERIN (UNII: PDC6A3C0OX)	5 mL in 100 mL
WATER (UNII: 059QF0KO0R)	11.68 mL in 100 mL

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75360-1125-1	50 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/01/2020	
2	NDC:75360-1125-2	65 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/01/2020	
3	NDC:75360-1125-4	250 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/01/2020	
4	NDC:75360-1125-5	1000 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/01/2020	
5	NDC:75360-1125-3	100 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/01/2020	
6	NDC:75360-1125-6	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/01/2020	
7	NDC:75360-1125-7	400 mL in 1 BAG; Type 0: Not a Combination Product	04/01/2020	



## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	505G(a)(3)	04/01/2020	

**Labeler** - Hemani International (645581294)

**Registrant** - Hemani International (645581294)

## Establishment

Name	Address	ID/FEI	Business Operations
Hemani International		645581294	manufacture(75360-1125)

Revised: 12/2023

Hemani International