

INNOVATIVE DISPLAY HAND SANITIZER- ethanol gel
HEALKINBIO CO.

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(s)

alcohol

Purpose

Purpose: Antiseptic

Use

☐ Hand sanitizing to help reduce bacteria on the skin

Warnings

- ☐ For external use only.
- ☐ Flammable, keep away from fire or flame.
- ☐ When using this product, avoid contact with the eyes. In case of contact, rinse eyes thoroughly with water.
- ☐ Stop use and ask a doctor if irritation or redness appears and lasts.
- ☐ Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center immediately.

Directions

☐ Take suitable amount of sanitizer in the hand. Wet thoroughly and rub hands together until dry

Other information

- ☐ Store in room temperature 0~30☐
- ☐ Period of Use: 36 Months after manufacturing date
- ☐ Manufacturing Date and No. Printed on bottle

Water, Carbomer, Triethanolamine, Polysorbate 20, Butylene Glycolm, Camellia Sinensis Leaf Extract, Tocopheryl Acetate, Fragrance

Drug Facts	
<u>Active Ingredients</u>	<u>Purpose</u>
alcohol 70% -----	Disinfecting Agent
<u>Uses</u>	
■ instant healthcare personnel hand antiseptic to reduce bacteria that potentially can cause disease	
■ instant hand antiseptic to decrease bacteria on the skin	

■ Instant hand antiseptic to decrease bacteria on the skin

Warning

For external use only

When using this product

■ if following abnormal symptoms persist, discontinue use
Irritation around the eyes, ears, mucous membranes, including the mouth, under the skin irritation and rashes

■ Stop immediately and consult a doctor if you experience

- 1) Hypersensitivity symptoms such as erythema, itching and dermatitis.
- 2) Skin Irritation
- 3) Following Instructions when using medication
 - (1) For external use only (Do not use internally)
 - (2) Avoid getting into the eyes (if contact occurs, wash well with clean water)

■ Be careful not to inhale or use excessively for a long time (ingesting ethanol repeatedly causes irritation to mucous membranes and headaches or other symptoms may appear. When used repeatedly in the same area, skin irritation may occur.

■ Do not use the product for a long time in the same area as swelling, inflammation or sickness may occur due to absorption through the skin. It is not recommended to use this on areas that have been medically treated with a cast or bandage.

■ Do not use in combination with soap or antibacterial cleansing agents.

Directions

■ Pour a small amount into hands, spread evenly and rub into the skin

Other Information

- read the directions and warnings before use
- avoid freezing and excessive heat above 40 degree C (104 degree F)

Inactive Ingredients

Water, Water, Carbomer, Triethanolamine, Polysorbate 20, Butylene Glycolm, Camellia Sinensis Leaf Extract, Tocopheryl Acetate, Fragrance

Questions or Comments? Call XXXX or email: XXXXXX

[DISTRIBUTED BY]

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[MANUFACTURED BY]

[PACKED BY]

INNOVATIVE DISPLAY HAND SANITIZER

ethanol gel

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:76586-114

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	70 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
CARBOMER 940 (UNII: 4Q93RCW27E)	
TROLAMINE (UNII: 9O3K93S3TK)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
WATER (UNII: 059QF0K00R)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76586-114-01	30 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/14/2020	
2	NDC:76586-114-02	30 mL in 1 POUCH; Type 0: Not a Combination Product	08/14/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	08/14/2020	

Labeler - HEALKINBIO CO. (694039685)

Establishment

Name	Address	ID/FEI	Business Operations
HEALKINBIO CO.		694039685	manufacture(76586-114)

Revised: 8/2020

HEALKINBIO CO.