FARMACY ANTISEPTIC HAND SANITIZER- alcohol gel GuStar Co Ltd

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

Active ingredients: ETHANOL 70% v/v

INACTIVE INGREDIENT

Inactive ingredients

Water, Glycerin, Carbomer, Dipropylene Glycol, Isopropylene Myristate, Triethanolamine, Citrus Paradisi (Grapefruit) Seed Extract, Aloe Barbadensis Leaf Juice Powder

PURPOSE

Purpose: ANTISEPTIC

WARNINGS

Warnings

For external use only. Flammable. Keep away from heat and flame

When using this product

keep out of eyes, ears, and mouth.

if contact occurs, rinse eyes thoroughly with water

Stop use and ask a doctor

if irritation or rash occurs.

KEEP OUT OF REACH OF CHILDREN

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

Uses

Uses

Hand sanitizer to help reduce bacteria on skin only when water and soap is not available

Directions

Directions

- Wet hands throughly with product and rub hands together until dry
- Supervise children under 6 years of age when using.

PACKAGE LABEL, PRINCIPAL DISPLAY PANEL



Drug Facts

Active Ingredients
Ethanol 70% v/v

Purpose Antiseptic

Uses

Hand Sanitizer to help reduce bacteria on the skin only when water and soap is not available.

Warnings

For external use only. Flammable. Keep away from heat and Flame.

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if irritation and rash occurs.

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- Wet hands thoroughly with product and rub hands together until dry.
- Supervise children under 6 years of age when using.

Inactive ingredients

Water, Glycerin, Carbomer, Dipropylene Glycol, Isopropyl Myristate, Triethanolamine, Citrus Paradisi (Grapefruit) Seed Extract, Aloe Barbadensis Leaf Juice Powder

MADE IN KOREA Distributed by Farmacy Beauty, LLC. 1111 MacArthur Blvd. Mahwah, NJ 07430 1-844-432-7622

FARMACY ANTISEPTIC HAND SANITIZER

alcohol gel

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:73819-0005

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name

Basis of Strength

ALCOHOL (UNII: 3K9958 V90M) (ALCOHOL - UNII:3K9958 V90M)

ALCOHOL (42 g in 60 mL

Inactive Ingredients Ingredient Name Strength Water (UNII: 059QF0KO0R) Glycerin (UNII: PDC6A3C0OX) CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC) Dipropylene Glycol (UNII: E107L85C40) ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS) Trolamine (UNII: 9O3K93S3TK) CITRUS PARADISI SEED (UNII: 12F08874Y7) ALOE VERA LEAF (UNII: ZY81Z83H0X)

Packaging								
#	Item Code	Package Description	Marketing Start Date	Marketing End Date				
1	NDC:73819-0005-	60 mL in 1 CONTAINER; 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 not final	part333E	04/01/2020					

Labeler - GuStar Co Ltd (694234583)

Registrant - GuStar Co Ltd (694234583)

Establishment							
Name	Address	ID/FEI	Business Operations				
GuStar Co Ltd		694234583	manufacture(73819-0005)				

Revised: 4/2020 GuStar Co Ltd