

HYGIENIGEL- hand sanitizer solution, gel forming / drops
HAIKOWER S.r.l.

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.

Hygienigel 75% Spray

Dosage and Admin

Place enough HYGIENIGEL on your hands and rub them until dry.

Children under 6 years of age must be supervised when using HYGIENIGEL.

Inactive Ingredients

Water, Melaleuca Alternifolia Leaf Oil, Chlorhexidine Digluconate, Glycerin, Benzalkonium Chloride

OTC - Active ingredient

Ethyl Alcohol 75% v/v

OTC - Ask Doctor section

Stop use and ask a doctor if irritation or rash appears and lasts.

OTC - Do not use

When using this product, do not ingest, inhale or use in or near the eyes. In case of contact, rinse thoroughly with water for at least 2 minutes.

OTC - Keep out of reach of children

Keep out of reach of children.

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

OTC - Purpose

Uses Hand Sanitizer to help reduce bacteria on the skin

Indication and usage

Uses Hand Sanitizer to help reduce bacteria on the skin

OTC _ Stop Use

Stop use and ask a doctor if irritation or rash appears and lasts.

When using this product, do not ingest, inhale or use in or near the eyes. In case of contact, rinse thoroughly with water for at least 2 minutes.

Warnings

- Flammable.
- Keep away from flame and fire.
- For external use only.

Package and Label

Flaconcino 100ml SPRAY

STAMPA 2 COLORI

 Pantone 294

 Pantone 485

etichetta bianco 120x70mm



HYGIENIGEL

hand sanitizer solution, gel forming / drops

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:78619-100

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	75 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
MELALEUCA ALTERNIFOLIA LEAF (UNII: G43C57162K)	
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)	
CHLORHEXIDINE GLUCONATE (UNII: MOR84MUD8E)	
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics

Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78619-100-01	100 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/26/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	02/26/2021	

Labeler - HAIKOWER S.r.l. (433503760)

Registrant - MELCHIONNA PLLC (039407173)

Establishment

Name	Address	ID/FEI	Business Operations
HAIKOWER S.r.l.		433503760	manufacture(78619-100) , label(78619-100) , pack(78619-100)