WANCARE ONEHAND ANTISEPTIC HAND GEL- ethyl alcohol gel
KAF GRUP SAGLIK HIZMETLERI INSAAT SANAYI VE TICARET LIMITED SIRKETI

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.

WANCARE ONEHAND ANTISEPTIC HAND GEL

DRUG FACTS

Active ingredient(s)

Ethyl Alcohol 70% (v/v)

Purpose

Antiseptic

Use(s)

Hand sanitizer to help reduce bacteria on the skin that could cause disease. Recommended for repeated use.

Warnings

For external use only.

Flammable. Keep away from fire 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, rinse eyes thoroughly with water. Do not inhale or ingest.

Stop use and ask a doctor if irritation or rash appears and lasts. Condition persists for more than 72 hours.

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

Directions

Place enough product in your palm to thoroughly cover your hands.

Rub hands together briskly until dry.

Children under 6 years of age should be supervised when using this product.

Other Information

Store between 5-40C (41-104F)

Avoid freezing and excessive heat above 40C (104F)

Inactive ingredients

Water (Aqua), Glycerin, Carbomer, Fragrance

70% ALCOHOL

Topical Gel

Manufacturer and License Owner:

KAF GRUP SAGLIK HIZMETLERI
INSAAT SANAYI VE TIC. LTD. STI.
Atakent Mah. 221. Sk. No:3A Rota Office A Blok
D:83
K.CEKMECE -ISTANBUL/TURKEY
Tel: +90 212 471 4 200
Fax: +90 212 471 4 201
www.kafgrup.com / info@kafgrup.com

Packaging

PACKAGE SIZE 5 mL

PACKAGE SIZE 50 mL

LOT

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www.kafgrup.com / info@kafgrup.com

50 ml℮ 1.7 fl. oz.
NDC xxxx-xxx-xx

8 682079 003803

WANCARE
ONEHAND

ANTISEPTIC HAND GEL

Topical Gel

70% ALCOHOL

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Other Information
Store between 5-40C (41-104F)
Avoid freezing and excessive heat above 40C (104F)

Inactive ingredients
Water (Aqua), Glycerin, Carbomer, Fragrance

PACKAGE SIZE 100 mL

LOT

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100 ml℮ 3.4 fl. oz.
NDC xxxx-xxx-xx

8 682079 003834

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ONEHAND

ANTISEPTIC HAND GEL

Topical Gel

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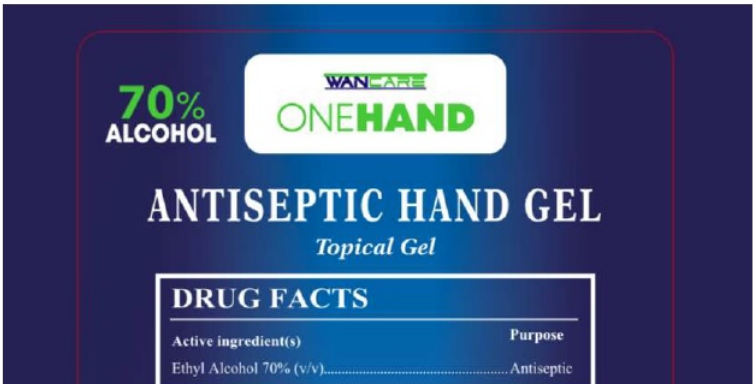
Other Information
Store between 5-40C (41-104F)
Avoid freezing and excessive heat above 40C (104F)

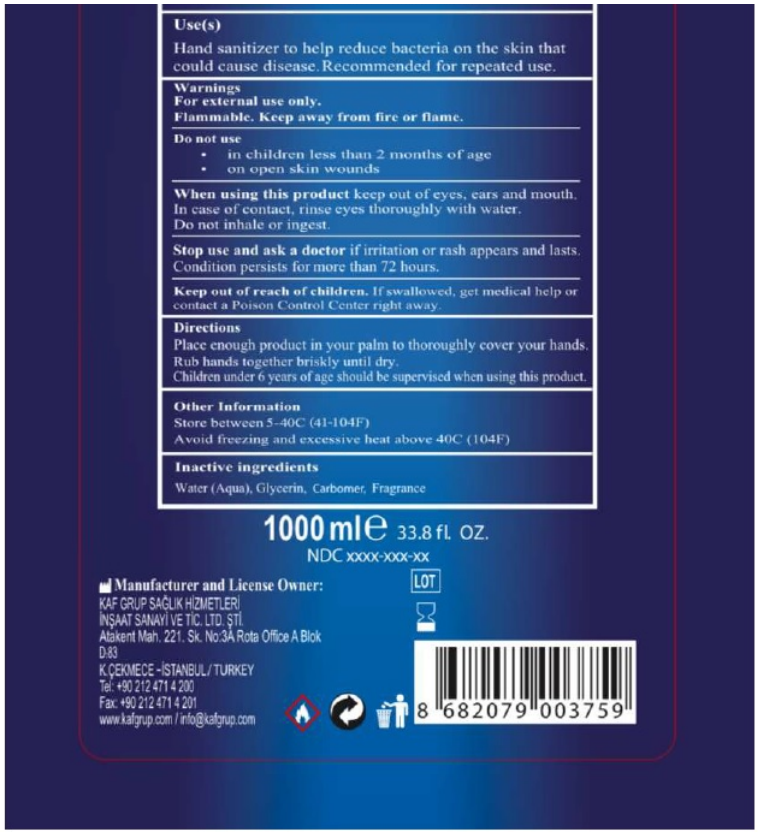
Inactive ingredients
Water (Aqua), Glycerin, Carbomer, Fragrance

PACKAGE SIZE 250 mL

PACKAGE SIZE 500 mL

PACKAGE SIZE 1000 mL





WANCARE ONEHAND ANTISEPTIC HAND GEL

ethyl alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:81314-201
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
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:81314-201-01	5 mL in 1 PACKET; Type 0: Not a Combination Product	12/18/2020	
2	NDC:81314-201-02	50 mL in 1 BOTTLE; Type 0: Not a Combination Product	12/18/2020	
3	NDC:81314-201-03	100 mL in 1 BOTTLE; Type 0: Not a Combination Product	12/18/2020	

4	NDC:81314-201-04	250 mL in 1 BOTTLE; Type 0: Not a Combination Product	12/18/2020	
5	NDC:81314-201-05	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	12/18/2020	
6	NDC:81314-201-06	1000 mL in 1 BOTTLE; Type 0: Not a Combination Product	12/18/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	12/18/2020	

Labeler - KAF GRUP SAGLIK HIZMETLERI INSAAT SANAYI VE TICARET LIMITED SIRKETI (519929115)

Establishment

Name	Address	ID/FEI	Business Operations
KAF GRUP SAGLIK HIZMETLERI INSAAT SANAYI VE TICARET LIMITED SIRKETI		519929115	manufacture(81314-201)

Revised: 12/2020 KAF GRUP SAGLIK HIZMETLERI INSAAT SANAYI VE TICARET LIMITED SIRKETI