

DETROX - DETRODERM GEL HAND AND SKIN ANTISEPTIC- isopropyl alcohol gel
DETRO HEALTHCARE KIMYA SANAYI ANONIM 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.

DETROX DETRODERM GEL HAND AND SKIN ANTISEPTIC

Drug Facts

Active ingredient

%70 Isopropyl Alcohol

Purpose

Antiseptic

Uses

Hygienic and surgical antisepsis of hands and skin. It is used at all health institutions like surgery, intensive care, clinics, dental clinics, laboratory, veterinary, patient care at home.

Warnings

Flammable. Keep out of ignition sources directly.

Do not use

Before reading user manual

After 6 months from cover opening

When using this product

No smoking. must not be contacted with powerful oxidants, alkali metals due to fire and explosion possibility. Keep out of reach of children, food, and animal foods. Keep out of ignition sources directly. Do not stock with oxidant and spontaneously combustible materials. Obey instructions existed in user manual.

Stop use and ask a doctor if

*In case of poisoning

*In case of ingestion

*In case of contact with eyes

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

Directions

For hygienic hand antisepsis, at least 3 ml solution is applied to hand without dilution and hands are rubbed until drying. For surgical hand antisepsis, 5 ml solution is applied to hand.

Other Information

Store containers tightly closed and in a well-ventilated area between 0 – 30°C and away from direct sunlight.

Do not use after expiry date.

Inactive ingredients

1,3-butanediol, glycerin, essence, carbomer, deionized water

Questions

You may also report serious side effects to this phone number (+1-XXX-XXX-XXXX)

Mon-Fri 9:00 AM - 5:00 PM

- Wide Effect Spectrum
- Alcohol Based
- Extensive Skin Compatability
- Usable at Dispenser

Email: international@detrox.com.tr

MADE IN TURKEY

Producer Name and Address:

Detro Healthcare Kimya Sanayi A.S.

Atatürk mh. Adnan Menderes cd.

No:7 Esenyurt/Istanbul-Turkey

Packaging



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ANTISEPTIC**

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1 (L) 33,8 fl oz

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Mon-Fri 9:00 AM - 5:00 PM

MADE IN TURKEY

Barcode: 8680097101464

PRODUCTION DATE: XXXXXX

LOT: XXXXXXXX

EXPIRY DATE: XXXXXXXX

Producer Name and Address:

Detro Healthcare Kimya Sanayi A.S.

Atatürk mh. Adnan Mendere cd.

No:7 Esenyurt/Istanbul-Turkey



isopropyl alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:79506-101
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302)	ISOPROPYL ALCOHOL	70 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
GLYCERIN (UNII: PDC6A3C0OX)	
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
WATER (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79506-101-01	100 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/30/2020	
2	NDC:79506-101-02	250 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/30/2020	
3	NDC:79506-101-03	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/30/2020	
4	NDC:79506-101-04	1000 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/30/2020	
5	NDC:79506-101-05	5000 mL in 1 CAN; Type 0: Not a Combination Product	06/30/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	06/30/2020	

Labeler - DETRO HEALTHCARE KIMYA SANAYI ANONIM SIRKETI(533133207)

Establishment

Name	Address	ID/FEI	Business Operations
DETRO HEALTHCARE KIMYA SANAYI ANONIM SIRKETI		533133207	manufacture(79506-101)

Revised: 7/2020

DETRO HEALTHCARE KIMYA SANAYI ANONIM SIRKETI