VITIUGEN INSTANT HAND SANITIZER- alcohol gel PHARMEST SAGLIK URUNLERI 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.

Active Ingredient(s)

Ethyl Alcohol 60%, Isopropyl Alcohol 10%

Purpose

Antiseptic, Hand Sanitizer

Use

Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.

Warnings

For external use only. Flammable. Keep away from heat 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 with eyes, rinse eyes thoroughly with water.

Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition. Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

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Directions

- Place enough product on hands to cover all surfaces. Rub hands together until dry.
- Supervise children under 6 years of age when using this product to avoid swallowing.

Other information

- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)

Inactive ingredients

Glycerin, Carbomer, Triethanolamine, Fragrance, Lavandula Angustifolia Flower Extract Pharmest Prod. date: 04.2020

Exp. date: 04.2023

Batch No: H20008

Vitiugen Instant Hand Sanitizer

Hand Clean & Protection Gel

Rinse Free

Non Sticky

Pharmest Saglik Urunleri

San. ve Tic. Ltd. Sti.

Orhan Gazi Mah. 18. Yol Sok. No:12

Esenyurt/Istanbul TURKEY



Prod Date : 04 2020

Exp. Date : 04.2023 Batch No : H20008

250 ml @ 8.45 fl oz



VITIUGEN Hand Clean&Protection Gel cleans your hands without the need for water and cares for your hands with intense glycerin and natural lavender oil. Provides maximum hygiene with plant based alcohol content.

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Pharmest









Prod Date : 04.2020 Exp. Date : 04.2023 Batch No : H20008

500 mle 16.9 fl oz

Instant Hand Sanitizer

HAND CLEAN & PROTECTION GEL



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Prod Date : 05.2020 Exp. Date : 05.2023

Batch No : H20009

100 mle 3.38 fl oz





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VITIUGEN INSTANT HAND SANITIZER

alcohol gel

Product Information

HUMAN OTC DRUG NDC:78984-001 Product Type Item Code (Source)

TOPICAL Route of Administration

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302)	ISOPROPYL ALCOHOL	10 mL in 100 mL	
ALCOHOL (UNII: 3K9958 V90M) (ALCOHOL - UNII:3K9958 V90M)	ALCOHOL	60 mL in 100 mL	

Inactive Ingredients	
Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0KO0R)	
LAVANDULA ANGUSTIFOLIA FLOWERING TOP (UNII: 9 YT4B71U8P)	
CARBOMER HOMO POLYMER, UNSPECIFIED TYPE (UNII: 0 A5MM307FC)	
TROLAMINE (UNII: 903K93S3TK)	

Product Characteristics		
Color	Score	
Shape	Size	
Flavor	Imprint Code	
Contains		

ŀ	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78984-001-50	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
2	NDC:78984-001-10	100 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
3	NDC:78984-001-25	250 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	

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Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	03/30/2020	

Labeler - PHARMEST SAGLIK URUNLERI SANAYI VE TICARET LIMITED SIRKETI (519827126)

Registrant - HARDAL GLOBAL CONSULTING LLC (123584960)

Establishment				
Name	Address	ID/FEI	Business Operations	
PHARMEST SAGLIK URUNLERI SANAYI VE TICARET LIMITED SIRKETI		519827126	manufacture(78984-001)	

Revised: 6/2020 PHARMEST SAGLIK URUNLERI SANAYI VE TICARET LIMITED SIRKETI