ABUTOL PARIS ANTISEPTIC HAND SANITIZER- ethyl alcohol gel ATAK FARMA KOZMETIK VE KIMYA SANAYI TICARET 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.

Abutol PARIS ANTISEPTIC HAND SANITIZER GEL CHERRY BLOSSOM SCENTED

Drug Facts

Drug Facts

Active ingredient

Ethyl alcohol 70%

Purpose

Antiseptic

Uses

- hand sanitizer to decrease bacteria on the skin
- recommended for repeated use
- for use when soap and water are not available

Warnings

Flammable, keep away from fire / flame For external use only

Do not use• in children less than 2 months of age

• on open skin wounds

When using this product • do not get into eyes. In case of contact, rinse eyes thoroughly with water. • Do not inhale or ingest.

Stop and ask doctor if

- irritation and redness develop
- 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

- wet hands thoroughly with product and allow to dry without wiping
- supervise children under 6 years of age when using this product to avoid swallowing

Other information

- store between 15-30°C (59-86°F)
- avoid freezing and excessive heat above 40°C (104°F)

• may discolor certain fabrics or surfaces

carbomer, FD&C Red No.40, fragrance, glycerin, triethanolamine, water.

Distributed by: Daisy Distribution LLC, Wood Ridge, NJ 07075 Country Of Origin: Turkey

You may also report any serious side effects to PO Box 328, Wood Ridge, NJ 07075-328

Lot No: 200620 Exp. Date: 06-2023 NDC: 77418-103-10

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•No Rinsing Required •Does Not Dry The Skin

ALCOHOL CONTENT 70%

Packaging



ANTISEPTIC HAND SANITIZER





CHERRY BLOSSOM SCENTED

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2.7 fl oz (80 mL)

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Inactive ingredients carbomer, FD&C Red No. 40, fragrance, glycerin, triethanolamine, water

Distributed by: Daisy Distribution LLC, Wood Ridge, NJ 07075 Made in Turkey

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ABUTOL PARIS ANTISEPTIC HAND SANITIZER

ethyl alcohol gel

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:77418-103

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
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0 A5MM307FC)	
FD&C Red No. 40 (UNII: WZB9127XOA)	
GLYCERIN (UNII: PDC6A3C0OX)	
TROLAMINE (UNII: 9O3K93S3TK)	
WATER (UNII: 059QF0KO0R)	

II	Packaging					
Ш	# Item Code	Package Description	Marketing Start Date	Marketing End Date		
	NDC:77418-103-10	1 in 1 CARTON	06/08/2020			
	1	80 mL in 1 TUBE; Type 0: Not a Combination Product				

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC monograph not final	part333A	06/08/2020			

Labeler- ATAK FARMA KOZMETIK VE KIMYA SANAYI TICARET ANONIM SIRKETI (566218248)

Establishment				
Name	Address	ID/FEI	Business Operations	
ATAK FARMA KOZMETIK VE KIMYA SANAYI TICARET ANONIM SIRKETI		566218248	manufacture(77418-103)	

Revised: 6/2020 ATAK FARMA KOZMETIK VE KIMYA SANAYI TICARET ANONIM SIRKETI