ABUTOL SANITIZING ALOE VERA- benzalkonium chloride spray 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 Sanitizing Spray Aloe Vera

Drug Facts

Active ingredient

Benzalkonium chloride 0.13%

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

For external use only. Protect from the sunlight.

Do not use

- on children less than 2 months of age
- on open skin wounds

When using this product • Avoid use on/or around eyes, ears, mouth, broken/irritated skin or large areas of body. In case of a contact with eyes, rinse thoroughly with water several minutes. do not inhale or ingest

Stop out of reach of children

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

Directions

• Hold upright at 6-7 inches away from surface and spray evenly. Repeat application a necessary when using this product to avoid swallowing

Other information

• store between 15-30 C (59-86F)

Inactive ingredients

Aqua, FD&C Blue No.1, FD&C Red No.40, Glycerin, Parfum.

* KILLS 99.9 OF MOST COMMON GERMS, BACTERIA AND VIRUSES.

Distributed by:

American Brands and More LLC, Wood Ridge, NJ 07075

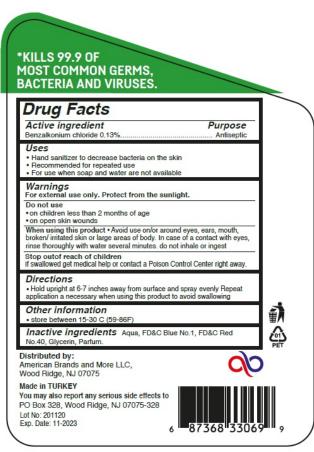
Made in TURKEY

You may also report any serious side effects to

PO Box 328, Wood Ridge, NJ 07075-328

Packaging





ABUTOL SANITIZING ALOE VERA

benzalkonium chloride spray

P	ro	duct	Information
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Product Type HUMAN OTC DRUG Item Code (Source) NDC:77418-803

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	0.13 g in 100 mL

Inactive Ingredients				
Ingredient Name	Strength			
WATER (UNII: 059QF0KO0R)				
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)				
FD&C RED NO. 40 (UNII: WZB9127XOA)				
GLYCERIN (UNII: PDC6A3C0OX)				

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:77418-803-	1000 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	11/06/2020	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333A	11/06/2020		

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(77418-803)	

Revised: 11/2020 ATAK FARMA KOZMETIK VE KIMYA SANAYI TICARET ANONIM SIRKETI