

ABUTOL ANTISEPTIC HAND WASH EUCALYPTUS- benzalkonium chloride liquid
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 WASH Eucalyptus

Drug Facts

Active ingredient

Benzalkonium chloride 0.12%

Purpose

Antiseptic

Uses

- for handwashing to decrease bacteria on the skin
- recommended for repeated use

Warnings

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

Stop use and ask a 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 and forearms. Apply 5 millilitre (teaspoonful) or palmful to hands and forearms. Scrub thoroughly for 20 seconds
- rinse and repeat
- 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)

Inactive ingredients

Aqua, Benzophenone-4, Citric Acid, Cocamide DEA, Cocamidopropyl Betaine, DMDM Hydantoin, FD&C Blue No.1, FD&C Yellow No.5, Glycerin, Methylchloroisothiazolinone, Methylisothiazolinone, Parfum, Sodium Chloride, Sodium Laureth Sulfate, Tetrasodium EDTA.

with Moisturizer

Eucalyptus - Cleans and soften hands

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
PARIS

**ANTISEPTIC
HAND
WASH**
with Moisturizer

Eucalyptus - Cleans and softens hands

16.9 fl oz (1pt 0.9 fl oz) (500 mL)

Drug Facts

Active ingredient	Purpose
Benzalkonium chloride 0.12%	Antiseptic

Uses

- for handwashing to decrease bacteria on the skin
- recommended for repeated use

Warnings
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

Stop use and ask a 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 and forearms. Apply 5 millilitre (teaspoonful) or palmful to hands and forearms. Scrub thoroughly for 20 seconds
- rinse and repeat
- 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)

Inactive ingredients Aqua, Benzophenone-4, Citric Acid, Cocamide DEA, Cocamidopropyl Betaine, DMDM Hydantoin, FD&C Blue No.1, FD&C Yellow No.5, Glycerin, Methylchloroisothiazolinone, Methylisothiazolinone, Parfum, Sodium Chloride, Sodium Laureth Sulfate, Tetrasodium EDTA.

ABUTOL ANTISEPTIC HAND WASH EUCALYPTUS			
benzalkonium chloride liquid			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77418-204
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	0.12 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
SULISOBENZONE (UNII: 1W6L629B4K)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
CO CO DIETHANOLAMIDE (UNII: 92005F972D)	
CO CAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	
DMDM HYDANTOIN (UNII: BYR0546TOW)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
GLYCERIN (UNII: PDC6A3C0OX)	
METHYLCHLOROISOTHIAZOLINONE (UNII: DEL7T5QRPN)	
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SODIUM LAURETH-3 SULFATE (UNII: BPV390UAP0)	
EDETATE SODIUM (UNII: MP1J8420LU)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77418-204-20	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	11/30/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	11/30/2020	

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(77418-204)

Revised: 11/2020

ATAK FARMA KOZMETIK VE KIMYA SANAYI TICARET ANONIM SIRKETI