

ABUTOL ANTISEPTIC HAND WASH OLIVE OIL AND ROSEMARY- 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 Olive Oil & Rosemary

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

water (aqua), benzophenone-4, citric acid, cocamide DEA, cocamidopropyl betaine, DMDM hydantoin, D&C Orange No. 4 , FD&C Blue No.1, glycerin, methylchloroisothiazolinone, methylisothiazolinone, fragrance, sodium chloride, sodium laureth sulfate, tetrasodium EDTA

with Moisturizer

Olive Oil & Rosemary

- Cleans and softens 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

Olive Oil & Rosemary - 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	
<ul style="list-style-type: none"> • for handwashing to decrease bacteria on the skin • recommended for repeated use 	
Warnings	
For external use only	
Do not use	
<ul style="list-style-type: none"> • 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	
<ul style="list-style-type: none"> • 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	
<ul style="list-style-type: none"> • 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	
<ul style="list-style-type: none"> • store between 15-30°C (59-86°F) • avoid freezing and excessive heat above 40°C (104°F) 	
Inactive ingredients water (aqua), benzophenone-4, citric acid, cocamide DEA, cocamidopropyl betaine, DMDM hydantoin, D&C Orange No. 4 , FD&C Blue No.1, glycerin, methylchloroisothiazolinone, methylisothiazolinone, fragrance sodium chloride, sodium laureth sulfate, tetrasodium EDTA	

ABUTOL ANTISEPTIC HAND WASH OLIVE OIL AND ROSEMARY

benzalkonium chloride liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77418-201
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)	
COCO DIETHANOLAMIDE (UNII: 92005F972D)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	
DMDM HYDANTOIN (UNII: BYR0546TOW)	
D&C ORANGE NO. 4 (UNII: Q1LIY3BO0U)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
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:77418-201-20	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	11/03/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	11/03/2020	

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(77418-201)

Revised: 11/2020

ATAK FARMA KOZMETIK VE KIMYA SANAYI TICARET ANONIM SIRKETI