

**ABUTOL ANTISEPTIC HAND WASH POMEGRANATE AND TANGERINE- 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.*

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**Abutol PARIS ANTISEPTIC HAND WASH Pomegranate & Tangerine**

***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 Red No. 40, Glycerin, Methylchloroisothiazolinone, Methylisothiazolinone, Parfum, Sodium Chloride, Sodium Laureth Sulfate, Tetrasodium EDTA.

**with Moisturizer**

**Pomegranate & Tangerine** -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

**Pomegranate & Tangerine** - Cleans and softens hands

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

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NDC: 77418-206-20

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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

Lot No: 200920  
Exp. Date: 09-2023

<b>ABUTOL ANTISEPTIC HAND WASH POMEGRANATE AND TANGERINE</b>			
benzalkonium chloride liquid			
<b>Product Information</b>			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:77418-206
<b>Route of Administration</b>	TOPICAL		
<b>Active Ingredient/Active Moiety</b>			
Ingredient Name	Basis of Strength	Strength	
<b>BENZALKONIUM CHLORIDE</b> (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 RED NO. 40 (UNII: WZB9127XOA)	
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:77418-206-20	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(77418-206)

Revised: 11/2020

ATAK FARMA KOZMETIK VE KIMYA SANAYI TICARET ANONIM SIRKETI