

**ABUTOL ANTISEPTIC HAND WASH LAVENDER AND JASMINE- 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 Lavender & Jasmine**

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

**with Moisturizer**

**Lavender & Jasmine**

- 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

NDC: 77418-202-20

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American Brands and More  
LLC, Wood Ridge, NJ 07075

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PO Box 328, Wood Ridge,  
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**ANTISEPTIC  
HAND  
WASH**  
with Moisturizer

**Lavender & Jasmine** - Cleans and softens hands

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

| <b>Drug Facts</b>   |                              |
|---|------------------------------|
| <b>Active Ingredient</b><br>Benzalkonium chloride 0.12%   | <b>Purpose</b><br>Antiseptic |
| <b>Uses</b><br>• for handwashing to decrease bacteria on the skin<br>• recommended for repeated use   |                              |
| <b>Warnings</b><br>For external use only<br><b>Do not use</b><br>• in children less than 2 months of age<br>• on open skin wounds<br><b>When using this product</b> • do not get into eyes. In case of contact, rinse eyes thoroughly with water<br><b>Stop use and ask a doctor if</b><br>• irritation and redness develop<br>• condition persists for more than 72 hours<br><b>Keep out of reach of children.</b> If swallowed, get medical help or contact a Poison Control Center right away. |                              |
| <b>Directions</b><br>• wet hands and forearms. Apply 5 millilitre (teaspoonful) or palmful to hands and forearms. Scrub thoroughly for 20 seconds<br>• rinse and repeat<br>• supervise children under 6 years of age when using this product to avoid swallowing  |                              |
| <b>Other Information</b><br>• store between 15-30°C (59-86°F)<br>• avoid freezing and excessive heat above 40°C (104°F)   |                              |
| <b>Inactive Ingredients</b> Aqua, Benzophenone-4, Citric Acid, Cocamide DEA, Cocamidopropyl Betaine, DMDM Hydantoin, FD&C Blue No.1, FD&C Red No. 40, Glycerin, Methylchloroisothiazolinone, Methylisothiazolinone, Parfum, Sodium Chloride, Sodium Laureth Sulfate, Tetrasodium EDTA.  |                              |

**ABUTOL ANTISEPTIC HAND WASH LAVENDER AND JASMINE**

benzalkonium chloride liquid

| <b>Product Information</b>     |                |                           |               |
|--------------------------------|----------------|---------------------------|---------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:77418-202 |
| <b>Route of Administration</b> | TOPICAL        |                           |               |

**Active Ingredient/Active Moiety**

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

**Inactive Ingredients**

| Ingredient Name                                 | Strength |
|---|----------|
| WATER (UNII: 059QF0KO0R)                        |          |
| SULISO BENZONE (UNII: 1W6L629B4K)               |          |
| CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)      |          |
| CO CO DIETHANOLAMIDE (UNII: 92005F972D)         |          |
| CO CAMIDO PROPYL BETAINE (UNII: 5OCF3O11KX)     |          |
| DMDM HYDANTOIN (UNII: BYR0546TOW)               |          |
| FD&C BLUE NO. 1 (UNII: H3R47K3TBD)              |          |
| FD&C RED NO. 40 (UNII: WZB9127XOA)              |          |
| GLYCERIN (UNII: PDC6A3C0OX)                     |          |
| METHYLCHLORO ISOTHIAZOLINONE (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:77418-202-20 | 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(77418-202) |

Revised: 11/2020

ATAK FARMA KOZMETIK VE KIMYA SANAYI TICARET ANONIM SIRKETI