

**ABUTOL ANTISEPTIC HAND WASH SPRING WATERFALL- 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 Spring Waterfall

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, Glycerin, Methylchloroisothiazolinone, Methylisothiazolinone, Parfum, Sodium Chloride, Sodium Laureth Sulfate, Tetrasodium EDTA.

with Moisturizer

Spring Waterfall - 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

NDC: 77418-205-20

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

Abutol
PARIS

**ANTISEPTIC
HAND
WASH**
with Moisturizer

**Spring
Waterfall** - 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, Glycerin, Methylchloroisothiazolinone, Methylisothiazolinone, Parfum, Sodium Chloride, Sodium Laureth Sulfate, Tetrasodium EDTA.

ABUTOL ANTISEPTIC HAND WASH SPRING WATERFALL

benzalkonium chloride liquid

Product Information

| | | | |
|-------------------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:77418-205 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|----------|
| BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - | BENZALKONIUM | 0.12 g |

| | | |
|------------------|----------|-----------|
| UNII:7N6JUD5X6Y) | CHLORIDE | 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 CAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX) | |
| DMDM HYDANTOIN (UNII: BYR0546TOW) | |
| 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:77418-205-20 | 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(77418-205) |

Revised: 11/2020

ATAK FARMA KOZMETIK VE KIMYA SANAYI TICARET ANONIM SIRKETI