

BLOOM WELLNESS- benzalkonium chloride patch
Radienz Living, LLC

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.

Redi Wipes Antibacterial Hand Wipes

Active ingredients

Benalkonium chloride 0.115%

Purpose

Antimicrobial

Uses

- For hand sanitizing to decrease bacteria on the skin.
- Recommended for repeated use.

Warnings

For external use only.

Do Not Use

Do not use over large areas of the body or if you are allergic to any of these ingredients.

When using this product

Avoid contact with eyes. If contact occurs, rinse eyes thoroughly with water.

Stop use and ask a doctor if

If irritation or redness develops and 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:

- To use, peel back label, pull out wipe and firmly reseal label to maintain package moisture. Do not remove label.

- Unfold cloth and rub thoroughly over all surfaces of both hands. Use only once and throw away. After cleansing, dispose of wipe in a trash receptacle. Rub hands together briskly to dry.

Inactive ingredients

Water, Behentrimonium Chloride, Dihydroxypropyl Peg-5 Linoleammonium Chloride, Glycereth-2 Cocoate, Aloe Barbadensis Leaf Extract, Tocopheryl Acetate (Vitamin E), Phenoxyethanol, Potassium Sorbate, Fragrance

Other Information

*Kills 99.9% of germs that may cause illness, including E. Coli and MRSA in just 15 seconds.

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DISTRIBUTED BY: U.S. NONWOVENS CORP. 100 EMJAY BLVD., BRENTWOOD, NY 11717

Principal Display Panel

bloom WELLNESS WIPES™

ANTIBACTERIAL HAND WIPES

FRESH SCENT

KILLS 99.9% OF GERMS*

DO NOT FLUSH

25 Wipes

7.4 IN x 7.2 IN (18.79cmx18.28 cm)

| | |
|---|---|
| <p>Drugs Facts (continued)</p> <p>Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.</p> <p>Directions</p> <ul style="list-style-type: none"> To use, peel back label, pull out wipe and firmly reseat label to maintain package moisture. Do not remove label. Unfold cloth and rub thoroughly over all surfaces of both hands. Use only once and throw away. After cleansing, dispose of wipe in a trash receptacle. Rub hands together briefly to dry. | <p>Inactive Ingredients</p> <p>Water, Behentrimonium Chloride, Dihydroxypropyl Peg-5 Linoleammonium Chloride, Glycereth-2 Cocostate, Aloe Barbadensis Leaf Extract, Tocopheryl Acetate (Vitamin E), Phenoxymethanol, Potassium Sorbate, Fragrance.</p> <p>*Kills 99.9% of germs that may cause illness, including E. Coli and MRSA in just 15 seconds.</p> |
|---|---|

25 WIPES 7.4 IN x 7.2 IN (18.79 cm x 18.28 cm)

ANTIBACTERIAL Hand Wipes

Kills 99.9% of Germs*

fresh scent




bloom™
WELLNESS

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| | |
|--|----------------|
| Drug Facts | |
| Active Ingredient | Purpose |
| Benzalkonium chloride 0.115% ... | Antimicrobial |
| Uses | |
| <ul style="list-style-type: none"> For hand sanitizing to decrease bacteria on the skin. Recommended for repeated use. | |
| Warnings | |
| For external use only. Do not use over large areas of the body or if you are allergic to any of these ingredients. | |
| When using this product | |
| <ul style="list-style-type: none"> Avoid contact with eyes. If contact occurs, rinse eyes thoroughly with water. | |
| Stop use and ask a doctor | |
| <ul style="list-style-type: none"> If irritation or redness develops and persists for more than 72 hours. | |



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100 ENWAY BLVD.
BRENTWOOD, NY 11717



BLOOM WELLNESS
benzalkonium chloride patch

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:52553-005 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-----------------------|--------------------|
| BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y) | BENZALKONIUM CHLORIDE | 0.115 mg in 100 mg |

Inactive Ingredients

| Ingredient Name | Strength |
|---|----------|
| WATER (UNII: 059QF0KO0R) | |
| BEHENTRIMONIUM CHLORIDE (UNII: X7GNG3S47T) | |
| DIHYDROXYPROPYL PEG-5 LINOLEAMMONIUM CHLORIDE (UNII: 0Y0NQR2GH1) | |
| GLYCERETH-2 (UNII: 0UY833L6XU) | |
| ALOE VERA LEAF (UNII: ZY81Z83H0X) | |
| .ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0) | |
| PHENOXYETHANOL (UNII: HIE492ZZ3T) | |
| POTASSIUM SORBATE (UNII: 1VPU26JZZ4) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:52553-005-25 | 25 in 1 PACKAGE | 03/16/2021 | |
| 1 | | 0.115 mg in 1 PATCH; Type 1: Convenience Kit of Co-Package | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC monograph not final | part333A | 03/16/2021 | |

Labeler - Radienz Living, LLC (117451061)

Registrant - Radienz Living, LLC (080453184)

Establishment

| Name | Address | ID/FEI | Business Operations |
|---------------------|---------|-----------|------------------------|
| Radienz Living, LLC | | 080453184 | manufacture(52553-005) |