

TERRASIL WOUND CARE - allantoin, benzethonium chloride ointment
Aidance Skincare & Topical Solutions, 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.

Drug Facts

Active Ingredient

Allantoin 0.5%

Benzethonium Chloride 0.1%

Purpose

Allantoin - Skin Protectant

Benzethonium Chloride - Antiseptic

Uses

- Helps protect skin and supports healing of minor cuts, scrapes, burns and wounds, including pressure sores, diabetic ulcers, cracked skin and lips.
- Topical antiseptic to help decrease the risk of skin infection.

Warnings

For external use only.

When using this product, do not get into eyes.

Stop use and ask a doctor if condition worsens, symptoms last more than 7 days or clear up and occur again within a few days.

Do not use on deep or puncture wounds, animal bites or serious burns.

Keep out of reach of children.

If swallowed, call poison control or seek medical help.

Directions

Wash and dry affected skin. Apply a thin layer of Terrasil. Cover affected area with a clean bandage. Repeat procedure 2-3 times daily until skin improves. Store at room temperature.

Inactive Ingredients

bentonite, cera alba (organic beeswax), magnesium oxide, peppermint oil, sage oil, silver oxide, simmondsia chinensis (jojoba) seed oil, tea tree oil, zinc oxide

PRINCIPAL DISPLAY PANEL - 14g Label

| | |
|---|-----------------|
| Drug Facts | |
| Active Ingredients | Purpose |
| Allantoin 0.5% | Skin Protectant |
| Benzethonium Chloride 0.1% | Antiseptic |
| Uses: • Helps protect skin and supports healing of minor cuts, scrapes, burns and wounds, including pressure sores, diabetic ulcers, cracked skin and lips. • Topical antiseptic to help decrease the risk of skin infection. | |
| Warnings: For external use only. When using this product, do not get into eyes. Stop use and ask a doctor if condition worsens, symptoms last more than 7 days or clear up and occur again within a few days. Do not use on deep or puncture wounds, animal bites or serious burns. Keep out of reach of children. If swallowed, call poison control or seek medical help. | |



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| Drug Facts (continued) |
| Directions: Wash and dry affected skin. Apply a thin layer of Terrasil. Cover affected area with a clean bandage. Repeat procedure 2-3 times daily until skin improves. Store at room temperature. |
| Inactive ingredients: bentonite, cera alba (organic beeswax), magnesium oxide, peppermint oil, sage oil, silver oxide, simmondsia chinensis (jojoba) seed oil, tea tree oil, zinc oxide |
| <small>Made in USA. Manufactured by Aidance Skincare 877-4-AIDANCE www.aidance.com Patented in US and international patents granted and pending. Terrasil™ and Activated Minerals™ are trademarks of Aidance Skincare and Topical Solutions LLC.</small> |

TERRASIL WOUND CARE

allantoin, benzethonium chloride ointment

Product Information

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|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:24909-117 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|--------------------------|-------------------|
| ALLANTOIN (UNII: 344S277G0Z) (ALLANTOIN - UNII:344S277G0Z) | ALLANTOIN | 0.5 g in 100 g |
| BENZETHONIUM CHLORIDE (UNII: PH41D05744) (BENZETHONIUM - UNII:1VU15B70BP) | BENZETHONIUM CHLORIDE | 0.1 g in 100 g |

Inactive Ingredients

| Ingredient Name | Strength |
|------------------------------------|----------|
| WHITE WAX (UNII: 7G1J5DA97F) | |
| BENTONITE (UNII: A3N5ZCN45C) | |
| JOJOBA OIL (UNII: 724GKU717M) | |
| MAGNESIUM OXIDE (UNII: 3A3U0GI71G) | |
| PEPPERMINT OIL (UNII: AV092KU4JH) | |
| SAGE OIL (UNII: U27K0H1H2O) | |
| SILVER OXIDE (UNII: 897WUN6G6T) | |
| TEA TREE OIL (UNII: VIF565UC2G) | |
| ZINC OXIDE (UNII: SOI2LOH54Z) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---------------------|----------------------|--------------------|
| 1 | NDC:24909-117-14 | 14 g in 1 JAR | | |
| 2 | NDC:24909-117-44 | 44 g in 1 JAR | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC monograph not final | part347 | 09/07/2012 | |

Labeler - Aidance Skincare & Topical Solutions, LLC (018950611)

Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---------|-----------|---|
| Aidance Skincare & Topical Solutions, LLC | | 018950611 | manufacture(24909-117) , label(24909-117) |

Revised: 9/2012

Aidance Skincare & Topical Solutions, LLC