# TERRASIL INFECTION PROTECTION WOUND CARE MAXIMUM STRENGTH- calendula, thuja occidentalis, symphytum officinale (comfrey) ointment Aidance Skincare & Topical Solutions, LLC

Disclaimer: This homeopathic product has not been evaluated by the Food and Drug Administration for safety or efficacy. FDA is not aware of scientific evidence to support homeopathy as effective.

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## terrasil INFECTION PROTECTION WOUND CARE Ointment MAXIMUM Strength

# **Active Ingredients**

Calendula 1X HPUS, Thuja occidentalis 6X HPUS, Symphytum Officinale (Comfrey) 1X HPUS *The letters HPUS indicate the component(s) in this product is (are) officially monographed in the Homeopathic Pharmacopeia of the United States* 

# **Purpose**

Calendula - Healing Agent, Thuja - Skin Eruption Relief, Symphytum Officinale (Comfrey)-Inflammatory Relief

#### Uses

Helps promote healing of cuts, scrapes and minor burns.

# 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. **Consult a doctor before using** 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 an ample amount of ointment. Cover with a clean bandage. Repeat procedure 1 to 3 times daily until skin improves or as directed by a doctor. Store at room temperature. May stain fabrics.

## **Inactive Ingredients**

beeswax (organic), bentonite (volcanic clay)\*\*, cotton seed oil, jojoba seed oil, magnesium oxide, peppermint oil, sage oil, silver oxide, tea tree oil, vegetable stearic acid (naturally sourced), zinc oxide.

\*\*may contain this ingredient.

#### PRINCIPAL DISPLAY PANEL - 50g Tube

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INFECTION PROTECTION WOUND CARE OINTMENT MAXIMUM STRENGTH



with Activated Minerals®



#### **DRUG FACTS**

Active Ingredients and Purpose: Calendula 1X HPUS - Healing Agent, Symphytum Officinale (Comfrey) 1X HPUS - Inflammatory Relief, Thuja Occidentalis 6X HPUS - Skin Eruption Relief. The letters HPUS indicate the component(s) in this product is (are) officially monographed in the Homeopathic Pharmacopeia of the United States. Uses: Helps promote healing of cuts, scrapes and minor burns. 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. Consult a doctor before using 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 an ample amount of ointment. Cover with a clean bandage. Repeat procedure 1 to 3 times daily until skin improves or as directed by a doctor. Store at room temperature. May stain fabrics, Inactive Ingredients: beeswax (organic), bentonite (volcanic clay)\*\*, cotton seed oil, jojoba seed oil, magnesium oxide, peppermint oil, sage oil, silver oxide, tea tree oil, vegetable stearic acid (naturally sourced), zinc oxide.

\*3X Faster reduction of bacteria compared to leading brands - data on file.

\*\*may contain this ingredient.

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#### TERRASIL INFECTION PROTECTION WOUND CARE MAXIMUM STRENGTH

calendula, thuja occidentalis, symphytum officinale (comfrey) ointment

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:24909-169

Route of Administration TOPICAL

| Active Ingredient/Active Moiety |
|---------------------------------|
| Ingredient Name                 |

Basis of Strength S

Strength

CALENDULA OFFICINALIS FLOWER (UNII: POM7O4Y7YD) (CALENDULA OFFICINALIS | CALENDULA OFFICINALIS | 1 [hp\_X]

| FLOWER - UNII:P0M7O4Y7YD)  | FLOWER                   | in 50 g             |
|--|--------------------------|---------------------|
| THUJA OCCIDENTALIS WHOLE (UNII: 5HBV6WCE3N) (THUJA OCCIDENTALIS WHOLE - UNII:5HBV6WCE3N) | THUJA OCCIDENTALIS WHOLE | 6 [hp_X]<br>in 50 g |
| COMFREY (UNII: D05HXK6R3G) (COMFREY - UNII:D05HXK6R3G)                                   | COMFREY                  | 1 [hp_X]<br>in 50 g |

| Inactive Ingredients                 |          |  |  |
|--------------------------------------|----------|--|--|
| Ingredient Name                      | Strength |  |  |
| WHITE WAX (UNII: 7G1J5DA97F)         |          |  |  |
| BENTONITE (UNII: A3N5ZCN45C)         |          |  |  |
| COTTONSEED OIL (UNII: H3E878020N)    |          |  |  |
| JOJOBA OIL (UNII: 724GKU717M)        |          |  |  |
| MAGNESIUM O XIDE (UNII: 3A3U0 GI71G) |          |  |  |
| PEPPERMINT OIL (UNII: AV092KU4JH)    |          |  |  |
| SAGE OIL (UNII: U27K0H1H2O)          |          |  |  |
| SILVER OXIDE (UNII: 897WUN6G6T)      |          |  |  |
| TEA TREE OIL (UNII: VIF565UC2G)      |          |  |  |
| STEARIC ACID (UNII: 4ELV7Z65AP)      |          |  |  |
| ZINC OXIDE (UNII: SOI2LOH54Z)        |          |  |  |

| P | Packaging        |  |                             |                           |  |
|---|------------------|--|-----------------------------|---------------------------|--|
| # | Item Code        | Package Description                                | <b>Marketing Start Date</b> | <b>Marketing End Date</b> |  |
| 1 | NDC:24909-169-14 | 14 g in 1 TUBE; Type 0: Not a Combination Product  | 07/01/2016                  |                           |  |
| 2 | NDC:24909-169-50 | 50 g in 1 TUBE; Type 0: Not a Combination Product  | 07/01/2016                  |                           |  |
| 3 | NDC:24909-169-20 | 200 g in 1 TUBE; Type 0: Not a Combination Product | 07/01/2016                  |                           |  |

| Marketing Information  |  |                      |                    |  |
|------------------------|--|----------------------|--------------------|--|
| Marketing Category     | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |  |
| unapproved homeopathic |  | 07/01/2016           |                    |  |
|                        |  |                      |                    |  |

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

| Establishment                             |         |           |  |  |
|---|---------|-----------|--|--|
| Name                                      | Address | ID/FEI    | Business Operations                      |  |
| Aidance Skincare & Topical Solutions, LLC |         | 018950611 | manufacture(24909-169), label(24909-169) |  |

Revised: 11/2018 Aidance Skincare & Topical Solutions, LLC