## TERRASIL JOCK-ITCH TREATMENT MAX- clotrimazole 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.

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#### **Drug Facts**

### **Active Ingredient**

Clotrimazole 1%

#### Purpose

Antifungal

#### Uses

Treats most jock itch (tinea cruris). For effective relief of itching, scaling, cracking, burning, redness, soreness, irritation, and discomfort associated with jock itch.

### Warnings

**For external use only. Do not use** on children under 2 years of age unless directed by a physician. Avoid contact with the eyes. If irritation occurs or if there is no improvement within 2 weeks, discontinue use and consult a physician **.** 

### Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away.

### Directions

Wash and dry affected skin. Apply a thin layer of ointment over the affected area twice daily (morning and night) or as directed by a doctor. Supervise children in the use of this product. Store at room temperature. May stain fabrics.

### **Inactive Ingredients**

beeswax (organic), jojoba seed oil, magnesium oxide, peppermint oil, sage oil, silver stearate, tea tree oil, witch hazel, zinc oxide

### **PRINCIPAL DISPLAY PANEL - 14 g tube**



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# TERRASIL JOCK-ITCH TREATMENT MAX

clotrimazole ointment

| Product Information   |                |                    |          |               |          |
|---|----------------|--------------------|----------|---------------|----------|
| Product Type  | HUMAN OTC DRUG | Item Code (Source) |          | NDC:24909-100 |          |
| Route of Administration   | TOPICAL        |                    |          |               |          |
|   |                |                    |          |               |          |
| Active Ingredient/Active  | Mojety         |                    |          |               |          |
| Ingredient Name Basis of  |                |                    |          |               | Strength |
| CLOTRIMAZOLE (UNII: G07GZ97H65) (CLOTRIMAZOLE - UNII:G07GZ97H65) CLOTRIMAZO |                |                    | -        | 1 g in 100 g  |          |
|   |                |                    |          |               |          |
| Institus Insuedients  |                |                    |          |               |          |
| Inactive Ingredients  |                |                    |          |               |          |
| Ingredient Name   |                |                    | Strength |               |          |
| SILVER STEARATE (UNII: 4H6PCLS  | 92ZN)          |                    |          |               |          |
| JOJOBA OIL (UNII: 724GKU717M)   |                |                    |          |               |          |
| MAGNESIUM OXIDE (UNII: 3A3U0  | GI71G)         |                    |          |               |          |
| PEPPERMINT OIL (UNII: AV092KU4  | 4JH)           |                    |          |               |          |
|   |                |                    |          |               |          |

SAGE OIL (UNII: U27K0H1H2O)

| WHITE WAX (UNII: 7G1/5DA97F)   |  |
|--------------------------------|--|
|                                |  |
| WITCH HAZEL (UNII: 101I4J0U34) |  |
| ZINC OXIDE (UNII: SOI2LOH54Z)  |  |

# Packaging

|                       | acted                 |   |                         |                       |  |  |  |  |
|-----------------------|-----------------------|---|-------------------------|-----------------------|--|--|--|--|
| #                     | Item Code             | Package Description                                       | Marketing Start<br>Date | Marketing End<br>Date |  |  |  |  |
| 1                     |                       | 14 g in 1 JAR; Type 1: Convenience Kit of Co-<br>Package  | 05/12/2014              | 12/31/2018            |  |  |  |  |
| 2                     |                       | 50 g in 1 TUBE; Type 0: Not a Combination<br>Product      | 05/12/2014              |                       |  |  |  |  |
| 3                     | NDC:24909-100-<br>44  | 44 g in 1 JAR; Type 0: Not a Combination Product          | 05/12/2014              | 05/23/2019            |  |  |  |  |
| 4                     |                       | 14 g in 1 TUBE; Type 1: Convenience Kit of Co-<br>Package | 05/12/2014              |                       |  |  |  |  |
| Marketing Information |                       |   |                         |                       |  |  |  |  |
|                       | Marketing<br>Category | Application Number or Monograph<br>Citation               | Marketing Start<br>Date | Marketing End<br>Date |  |  |  |  |
| ОТ                    | C monograph fina      | al part333C   | 05/12/2014              |                       |  |  |  |  |
|                       |                       |   |                         |                       |  |  |  |  |

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

| Establishment                              |         |           |                            |  |  |  |  |  |  |
|--|---------|-----------|----------------------------|--|--|--|--|--|--|
| Name                                       | Address | ID/FEI    | <b>Business Operations</b> |  |  |  |  |  |  |
| Aidance Skincare and Topical Solution, LLC |         | 018950611 | manufacture(24909-100)     |  |  |  |  |  |  |

Revised: 5/2023

Aidance Skincare & Topical Solutions, LLC