

ANTIFUNGAL MEDICATED BAR- tolnaftate soap
Haikou Pucao Trading Co.,Ltd

RoyceDerm antifungal soap

Tolnaftate 1%

anti-fungal

Cures & prevents most athlete's foot(tinea pedis), jock itch(tinea cruris) & ringworm (tinea corporis).

Relieves itching, irritation, redness, scaling, and discomfort associated with these conditions.

Forx external use only

on children under 2 years of age except under the advice and supervision of a doctor.

avoid contact with the eyes. If contact occurs, rinse the eyes thoroughly with water.

if condition worsens or does not improve after 4 weeks of regular use as directed.

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

Wash the affected area thoroughly with water.

Lather the soap and apply it to the affected area.

Allow the lather to sit on the skin for 2-3 minutes before rinsing thoroughly.

For athlete's foot: pay special attention to spaces between the toes; wear well-fitting, ventilated shoes, and change shoes and socks at least once daily.

Use 1-2 times daily for 4 weeks; if the condition persists longer, consult a doctor.

Supervise children in the use of this product.

Store at room temperature.

Protect from freezing.

Melaleuca Alternifolia (Tea Tree) Leaf Oil, Aqua (Water), Sorbitol, Elaeis Guineensis (Palm) Oil, Cocos Nucifera (Coconut) Oil, Olea Europaea (Olive) Fruit Oil, Propylene Glycol, Glycerin, Stearic Acid, Lauric Acid, Myristic Acid, Sodium Myristate, Sodium Glutamate, Sodium Hydroxide, Sodium Dodecylbenzene Sulfonate, Sulfur, Hamamelis Virginiana (Witch Hazel) Extract, Ceramide NP.

Visit at www.roycederm.com



3545 CP CMYK: 71, 0, 11, 0
628 CP CMYK: 25, 0, 4, 0
4159 CP CMYK: 100, 38, 0, 37

ANTIFUNGAL MEDICATED BAR

tolnaftate soap

Product Information

| | | | |
|-------------------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:85261-001 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--------------------------------------------------------------|-------------------|--------------|
| TOLNAFTATE (UNII: 06KB629TKV) (TOLNAFTATE - UNII:06KB629TKV) | TOLNAFTATE | 10 mg in 1 g |

Inactive Ingredients

| Ingredient Name | Strength |
|---------------------------------------------------------------|----------|
| MELALEUCA ALTERNIFOLIA (TEA TREE) LEAF OIL (UNII: VIF565UC2G) | |
| OLEA EUROPAEA (OLIVE) FRUIT OIL (UNII: 6UYK2W1W1E) | |
| WATER (UNII: 059QF0KO0R) | |
| CERAMIDE NP (UNII: 4370DF050B) | |
| SULFUR (UNII: 70FD1KFU70) | |
| SORBITOL (UNII: 506T60A25R) | |
| LAURIC ACID (UNII: 1160N9NU9U) | |
| ELAEIS GUINEENSIS (PALM) OIL (UNII: 5QUO05548Z) | |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |

| | |
|-------------------------------------------------------------------------|--|
| GLYCERIN (UNII: PDC6A3C0OX) | |
| SODIUM DODECYLBENZENESULFONATE (UNII: 554127163Y) | |
| SODIUM MYRISTATE (UNII: 06BLC4V0IV) | |
| SODIUM GLUTAMATE (UNII: W81N5U6R6U) | |
| COCOS NUCIFERA (COCONUT) OIL (UNII: Q9L0O73W7L) | |
| STEARIC ACID (UNII: 4ELV7Z 65AP) | |
| MYRISTIC ACID (UNII: 0I3V7S25AW) | |
| HAMAMELIS VIRGINIANA (WITCH HAZEL) LEAF WATER (UNII: 8FP93ED6H2) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|------------------------------------------------------|----------------------|--------------------|
| 1 | NDC:85261-001-01 | 232 g in 1 CARTON; Type 0: Not a Combination Product | 04/20/2025 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|------------------------------------------|----------------------|--------------------|
| OTC Monograph Drug | M005 | 04/20/2025 | |

Labeler - Haikou Pucao Trading Co.,Ltd (621948245)

Registrant - Haikou Pucao Trading Co.,Ltd (621948245)

Revised: 3/2025

Haikou Pucao Trading Co.,Ltd