

FUNGINIX JOCK ITCH TREATMENT- tolnaftate cream

The Sisquoc Healthcare Corporation

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.

FUNGINIX JOCK ITCH TREATMENT

ACTIVE INGREDIENT

TOLNAFTATE 1%

PURPOSE

ANTIFUNGAL

USES

- ANTI-FUNGAL TREATMENT

WARNINGS

FOR EXTERNAL USE ONLY.

DO NOT USE ON CHILDREN UNDER 2 YEARS OF AGE UNLESS DIRECTED BY A DOCTOR.

WHEN USING THIS PRODUCT AVOID CONTACT WITH THE EYES. IF CONTACT OCCURS, RINSE THE EYES VERY THOROUGHLY WITH WATER.

STOP USE AND ASK A DOCTOR IF IRRITATION OCCURS OR THERE IS NO IMPROVEMENT WITHIN 4 WEEKS.

KEEP OUT OF REACH OF CHILDREN. IF SWALLOWED, GET MEDICAL HELP OR CONTACT A POISON CONTROL CENTER RIGHT AWAY.

DIRECTIONS

- For the cure of all forms of jock itch. For relief of itching, scaling, cracking, burning, redness, soreness, irritation and discomforts which may accompany these conditions.
- Wash affected area and dry thoroughly. Apply a layer of FUNGINIX Jock Itch Treatment over the affected area twice daily (morning and night). Allow the cream to dry for at least 3 minutes before covering the affected area with clothing.
- Wash hands after each application to prevent the chance of the infection spreading to other parts of the skin.
- Most jock itch infections will require at least 2 weeks of continuous daily treatment before the infection is completely eliminated.
- Proper use of FUNGINIX Jock Itch Treatment should eliminate all types of fungal infections. If the condition persists longer, contact a physician or medical professional.

INACTIVE INGREDIENTS

Water, Prunus Amygdalus Dulcis (Sweet Almond) Oil, Oleth-10 Phosphate, Triethanolamine, Polysorbate 20, Acrylates Copolymer, Glycerin, Propylene Glycol, Uva Ursi (Bearberry) Extract, Beta-Glucan, Propolis Extract, Aloe Barbadosis Juice, Tocopheryl Acetate (Vitamin E), Camphor, Menthol, Melaleuca Alternifolia (Tea Tree) Leaf

Oil, Lavandula Angustifolia (Lavender) Oil, Jasminum Officinale (Jasmine) Oil, Eugenia Caryophyllus (Clove) Flower Oil, Theobroma Cacao (Cocoa) Seed Butter, Rosa Canina (Rose Hip) Flower Oil, Cetyl Hydroxyethylcellulose, Ethylhexylglycerin, Phenoxyethanol

Store between 20°C to 25°C (68° to 77°F)

MAXIMUM STRENGTH

FUNGINIX

JOCK ITCH TREATMENT

1 OZ / 28 G

Active Ingredient: Tolnaftate 1%

WARNINGS: For external use only. Do not use on children under 2 years of age unless directed by a doctor. **When using this product**, avoid contact with eyes. If contact occurs, rinse eyes thoroughly with water.

Stop use and ask a physician if irritation occurs or if there is no improvement within 4 weeks. **Keep out of reach of young children.** If swallowed, get medical assistance or contact a poison control center.

Directions: Wash affected area and dry thoroughly. Apply a thin layer over affected area twice daily (morning and night). Use daily for 2 weeks, if condition persists longer, seek medical advice. This product is not effective on scalp or nails.

Other Information: Store between 20° to 25°C (68° to 77°F)

Distributed By: Sisquoc Healthcare, Inc. Newport Beach, CA 92660 U.S.A. © 2019

MAXIMUM STRENGTH

FUNGINIX

JOCK ITCH TREATMENT

Specifically designed to eliminate jock itch with our extensive list of anti-fungal ingredients.

WHAT IS JOCK ITCH?

Jock Itch, known medically as tinea cruris, is a common skin infection of the groin, buttocks and inner thigh caused by fungus. Signs and symptoms often include itching, scaling, and

longer visible. All fungal infections, like jock itch, often return if the treatment period is not thorough enough to kill ALL of the fungal agents. Not just the part of the infection that is visible. In stubborn cases which show no signs of substantial progress, it is best to seek a medical professional to discuss alternative methods of treatment.

DIRECTIONS:

- For the cure of all forms of jock itch. For relief of itching, scaling, cracking, burning, redness, soreness, irritation and discomforts which may accompany these conditions.
- Wash affected area and dry thoroughly. Apply a layer of FUNGINIX Jock Itch Treatment over the affected area twice daily.

redness. In severe cases the skin may blister. Jock Itch fungus may infect any part of the middle of the body, but most often grows in the folds of the skin between the inner thighs and groin. The same fungus may also affect the nails, hands or feet. It is a member of the larger group of skin infections known as tinea. Tinea cruris is caused by a number of different fungi called dermatophytes. The condition is typically acquired by coming into contact with infected skin or clothing. Common places where the fungi can survive are around swimming pools and in locker rooms. Usually diagnosis is made based on signs and symptoms.

Some methods of prevention include keeping the infected area clean and dry, changing clothes every day and wearing loose fitting garments. When infected, the area should be kept dry. Treatment can be either with an antifungal medication like FUNGINIX AF which is applied to the skin such as tolnaftate or for persistent infections antifungal medication that are taken by mouth such as terbinafine. Use of any antifungal cream is typically recommended for a minimum of four weeks.

WHY USE FUNGINIX TO ELIMINATE JOCK ITCH?

FUNGINIX Jock Itch Treatment is an excellent combination of anti-fungal agents, essential oils and fungus-fighting extracts specifically created to fight jock itch. In order to create the most powerful anti-fungal solution, we at Sisquoc Healthcare took the best of research from both traditional and natural medicine on how to kill the fungi responsible for jock itch infections.

After comparing and contrasting the effects of various combinations, we came up with our unique blend of active ingredients like Tolnaftate, herbal remedies like camphor and essential oils like tea tree oil. There is simply no other topical treatment created to fight jock itch that is more effective and complete.

HOW LONG SHOULD TREATMENT LAST?

treatment over the affected area twice daily (morning and night). Allow the cream to dry for at least 3 minutes before covering the affected area with clothing.

- Wash hands after each application to prevent the chance of the infection spreading to other parts of the skin.
- Most jock itch infections will require at least 2 weeks of continuous daily treatment before the infection is completely eliminated.
- Proper use of FUNGINIX Jock Itch Treatment should eliminate all types of fungal infections. If the condition persists longer, contact a physician or medical professional.

WARNINGS:

- Use only as directed. For external use only.
- Ask a doctor before using on children under 2 years of age.
- When using this product, avoid contact with eyes.
- Stop using and consult a physician if the condition continues and there is no improvement within 4 weeks.
- **Keep out of reach of children.** If swallowed, get medical help or contact a poison control center right away.

Active Ingredient: Tolnaftate (1%)

Inactive Ingredients: Water, Prunus Amygdalus Dulcis (Sweet Almond) Oil, Oleth-10 Phosphate, Triethanolamine, Polysorbate 20, Acrylates Copolymer, Glycerin, Propylene Glycol, Uva Ursi (Bearberry) Extract, Beta-Glucan, Propolis Extract, Aloe Barbadensis Juice, Tocopheryl Acetate (Vitamin E), Camphor, Menthol, Melaleuca Alternifolia (Tea Tree) Leaf Oil, Lavandula Angustifolia (Lavender) Oil, Jasminum Officinale (Jasmine) Oil, Eugenia Caryophyllus (Clove) Flower Oil, Theobroma Cacao (Cocoa) Seed Butter, Rosa Canina (Rose Hip) Flower Oil, Cetyl Hydroxyethylcellulose, Ethylhexylglycerin, Phenoxyethanol

The active ingredient in FUNGINIX Jock Itch Treatment has been recognized to be safe and effective by an FDA Expert Advisory Panel, when used as directed.

Jock Itch infections should be treated the moment the infection is detected. The earlier you begin treating the infected areas, the shorter the treatment period will be. Once treatment with FUNGINIX Jock Itch Treatment begins, it should be uninterrupted for a minimum of 2 weeks. More severe treatments may require up to 4-6 months to eliminate all existing fungal agents. It is VERY IMPORTANT to continue treatment beyond the time when the infection is no



SISQUOC
HEALTHCARE, INC.

Sisquoc Healthcare, Inc.
Newport Beach, CA 92660 USA
Questions? (800) 589-8913

FUNGINIX JOCK ITCH TREATMENT

tolnaftate cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71229-104
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TOLNAFTATE (UNII: 06KB629TKV) (TOLNAFTATE - UNII:06KB629TKV)	TOLNAFTATE	1 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
ALMOND OIL (UNII: 66YXD4DKO9)	
OLETH-10 PHOSPHATE (UNII: Q95361F4VS)	
TROLAMINE (UNII: 9O3K93S3TK)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
BUTYL ACRYLATE/METHYL METHACRYLATE/METHACRYLIC ACID COPOLYMER (18000 MW) (UNII: JZ1374NL9E)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
ARCTOSTAPHYLOS UVA-URSI WHOLE (UNII: 37SXO36KR7)	
OAT (UNII: Z6J799EAJK)	
PROPOLIS WAX (UNII: 6Y8XYV2NOF)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
CAMPHOR OIL (UNII: 75IZZ8Y727)	
MENTHOL (UNII: L7T10EIP3A)	
TEA TREE OIL (UNII: VIF565UC2G)	
LAVANDULA ANGUSTIFOLIA WHOLE (UNII: 51217XIL5L)	
JASMINUM OFFICINALE WHOLE (UNII: X3314B4SYD)	
CLOVE LEAF OIL (UNII: VCA5491KVF)	
COCOA BUTTER (UNII: 512OYT1CRR)	

ROSA CANINA FRUIT OIL (UNII: CR7307M3QZ)	
CETYL HYDROXYETHYLCELLULOSE (350000 MW) (UNII: T7SWE4S2TT)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71229-104-11	28 g in 1 TUBE; Type 0: Not a Combination Product	03/25/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333C	03/25/2019	

Labeler - The Sisquoc Healthcare Corporation (021517142)

Establishment

Name	Address	ID/FEI	Business Operations
COASTAL CONTRACT PACKAGING, INC.		137341611	manufacture(71229-104)

Revised: 1/2020

The Sisquoc Healthcare Corporation