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PRODUCT NAME: Ritemed Tolnaftate and Insert	PPC No.: PPC-18-0711	SIZE: 148x148mm	Drawing no. / Dieline no.	COLOR: P287C	RPD NO.: 44713 REVISION NO.: 01 REVISION DATE: 07-12-18

APPROVED BY:

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TSG	MARKETING	TSG SUPERVISOR	R & D	QA	PSD

148 mm

148 mm

RiteMED®

C7EW

TOLNAFTATE

10 mg / g Ointment

ANTIFUNGAL

FORMULATION

Each gram contains:

Tolnaftate, USP.....10 mg

Tolnaftate, a thioester of β-naphthol, is a synthetic antifungal drug with either fungicidal or fungistatic property that is used to treat ringworm, athlete's foot and jock itch.

It is a selective, reversible and non-competitive inhibitor of membrane-bound squalene-2, 3-epoxidase, an enzyme involved in the biosynthesis of ergosterol. Inhibition leads to the accumulation of squalene and a deficiency in ergosterol, an essential component of fungal cell walls, thereby increasing membrane permeability, disrupting cellular organization and causing cell death. In addition, this agent may also distort the hyphae and stunts mycelial growth in susceptible fungi.

INDICATIONS

Tolnaftate, 10 mg/g ointment, is an effective fungicide against dermatophytes - *Malassezia furfur* , *Epidermophyton floccosum* and species of *Trichophyton (T. rubrum, T. mentaggrophytes, T. tonsurans) and Microsporum (M. canis, M. audouini, M. gypseum)* - that cause superficial *tinea* infections such as *tinea pedis, tinea cruris, tinea manuum* and *tinea corporis.*

The cure rate for *tinea pedis* is about 80%.

Tolnaftate is also effective against *Pityrosporum obiculare* and is used in the treatment of pityriasis versicolor.

The drug does not suppress *Candida* and is ineffective against bacterial infections.

DOSAGE AND ADMINISTRATION

Tolnaftate is applied to affected part of the skin and surrounding areas twice daily. The treatment duration may last from 2 to 6 weeks.

When necessary, application of tolnaftate may be repeated.

PHARMACOKINETICS

There is minimal absorption from the skin with topical application of tolnaftate 10 mg/g ointment.

ADVERSE EFFECT

Allergic and toxic reactions such as contact dermatitis and irritation are rarely reported with the use of topical tolnaftate.

Burning sensation and maceration at the area of the lesion are also occasionally reported with the use of tolnaftate which are said to be caused by endotoxins of fungi that were eradicated.

PRECAUTIONS

Tolnaftate is not used to treat deep infections of hair follicles or of nail beds.

Concomitant use of tolnaftate with griseofulvin, a systemic drug, may be considered when treating infections in hyperkeratotic lesions or in the palms and soles which are normally thick in layers.

Do not apply tolnaftate near the eyes, mouth, nose, vagina, and other mucous membranes.

ADVERSE DRUG REACTION REPORTING STATEMENT

For suspected adverse drug reaction, seek medical attention immediately and report to the FDA at www.fda.gov.ph and Unilab at (+632) 858-1000 or productsafety @unilab.com.ph. By reporting undesirable effects, you can help provide more information on the safety of this medicine.

STORAGE CONDITION

Store at temperatures not exceeding 25°C.

REFERENCES:

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2. Sweetman S (Ed). Martindale: The Complete Drug Reference. London: Pharmaceutical Press Electronic version, (2007).
3. http://www.medicinescomplete.com/mc/martindale/current/5801-a.htm
4. Gennaro AR (Ed). Remington's Pharmaceutical Sciences, 17th Ed. Pennsylvania: Mack Publishing Company, 1985.
5. Gilman AG, Rall TW, Nies AS, et al. Goodman and Gilman's The Pharmacological Basis of Therapeutics. International Edition. Singapore: McGraw Hill Book Co., 1992.
6. Katzung B (Ed). Basic and Clinical Pharmacology, 6th ed. Connecticut: Appleton & Lange, 1995.
7. www.medscape.com

AVAILABILITY

RiteMED® Tolnaftate 10 mg/g Ointment, in 15 grams Tube

Manufactured by Interphil Laboratories, Inc.
Canlubang Industrial Estate
Bo. Pittland, Cabuyao, Laguna
Distributed by **RiteMED Phils., Inc.**
56 EDSA, Mandaluyong City, Philippines

Date of FDA Approval: January 26, 2018
Date of Revision of Package Insert: May 2018

DRP-1910-03

RTM700270IN01

Reg. IPOPHIL

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