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PHYTODERM® COMPOSITUM

OINTMENT

Composition

Active Ingredient

Tolnaftate	1%
Salicylic acid	3%
Benzoic acid	6%

Other Ingredients

Polyethylene glycol 400, polyethylene glycol 4000, white vaseline, butylated hydroxytoluene.

Mechanism of Action

Phytoderm Compositum contains tolnaftate, a highly active synthetic fungicidal agent effective in the treatment of superficial fungal infections of the skin. It is virtually non-sensitizing, and does not ordinarily sting or irritate intact skin.

Phytoderm Compositum combines tolnaftate with the classic keratolytic combination, salicylic acid and benzoic acid, known as the Whitfield combination. The Whitfield combination has a dual role in Phytoderm Compositum – to remove the thick keratin layers which serve as substrate for fungus invasion and enhance the penetration of tolnaftate.

Phytoderm Compositum is therefore intended for the treatment of areas of the skin where the keratin layers are thick, as on the palms of the hands and soles of the feet.

Indications

Superficial dermatomycoses where a keratolytic effect is also required.

Contraindications

Known hypersensitivity to any of the components of the preparation.

Warnings

For external use only.

In case of sensitization or irritation due to Phytoderm Compositum, or if the patient's skin disease does not improve within 10 days or becomes worse during self medication with this product, treatment should be discontinued and the patient should consult the physician.

Phytoderm Compositum is not intended to be used in the eyes.

Phytoderm Compositum should be kept out of the reach of children.

Due to the salicylic acid component, this product should not be used in the following situations;

Patients presenting with diabetes mellitus or peripheral vascular disease, since acute inflammation or ulceration may occur, especially on the extremities.

Patients presenting with inflammation, irritation, or infection of the skin.

Phytoderm Compositum should not be used for the treatment of dermatophyte infections that occur on the scalp or nails.

Patients presenting with moles and birthmarks.

Use in Pregnancy and Breastfeeding

Safety of use of this product has not been established. However, due to the possible systemic absorption of salicylic acid, there is concern regarding the possibility of the premature closure of the ductus arteriosus in the fetus. It is also not known whether tolnaftate is distributed into milk. Therefore, the potential benefit to the mother should be weighed versus the possible risk to the fetus when this product is used in pregnant or nursing mothers.

Use in Pediatrics

This medicine is not generally intended to be used in children under 2 years of age, unless clearly directed by the physician.

Adverse Reactions

Phytoderm Compositum is essentially non-sensitizing. A few cases of sensitization or mild irritation have been reported.

Tolnaftate has a low order of toxicity and a low index of sensitization when applied topically. Slight local irritation may occur when applied to excoriated skin or when secondary, superimposed infections are present over a large area of skin. At least one case of sensitization to butylated hydroxytoluene which is present in the tolnaftate formulations has been confirmed.

Precautions

Prior to the institution of therapy, the diagnosis of a superficial mycotic infection must be confirmed. If the skin condition becomes worse to mixed infections of bacteria or non-susceptible fungi, the treatment should be discontinued. If no improvement occurs within four weeks of treatment, the diagnosis should be reviewed.

In mixed infection where bacteria or non-susceptible fungi such as *Candida albicans* are present, supplementary topical or systemic anti-infective therapy is indicated.

Directions for Use

Apply to the affected areas 2-3 times daily.

Registration Number:

052 66 20178 00.

Storage

Store below 25°C.

Manufacturer

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