

This insert contains basic prescribing information only. For more comprehensive information, a PROFESSIONAL BROCHURE is available to physicians on request.

TINADERM Solution

Brand of tolnaftate , U.S.P.

Each ml contains
10 mg of Tolnaftate U.S.P.

FOR DERMATOLOGIC USE
NOT FOR OPHTHALMIC, ORAL OR INTRAVAGINAL USE

DESCRIPTION: Each ml of TINADERM solution contains 10 mg of tolnaftate. TINADERM solution provides safe and effective concentrations of tolnaftate and is useful in treating a wide variety of cutaneous fungal and yeast-produced infections. Tolnaftate is a synthetic thiocarbamate antifungal agent. Tolnaftate is a nonsensitizing highly active synthetic fungicidal agent that is markedly effective in the treatment of superficial fungal infections of the skin. TINADERM solution does not ordinarily sting or irritate intact or broken skin, and is inactive systemically. TINADERM solution does not stain or discolour skin, hair, nails or clothing.

PHARMACOLOGY:

Tolnaftate is a synthetic thiocarbamate antifungal agent. The exact mode of action of tolnaftate is not known, but the drug has been demonstrated to distort the hyphae and stunt mycelial growth in susceptible fungi. Tolnaftate is active in vitro against *Microsporum audouinii*, *M. canis*, *M. gypseum*, *M. japonicum*, *Trichophyton mentagrophytes*, *T. rubrum*, *T. schoenleinii*, *T. tonsurans*, and *Epidermophyton floccosum*. Tolnaftate is inactive against *Candida albicans*, *Cryptococcus neoformans*, and most strains of *Aspergillus fumigatus*. TINADERM solution provides excellent topical treatment of cutaneous mycotic infections such as tinea pedis, tinea cruris, tinea corporis, tinea barbae and tinea manuum.

INDICATIONS: Treatment and prophylaxis of superficial dermatophyte infections and treatment of tinea versicolor.

DOSAGE & ADMINISTRATION: A sufficient quantity of TINADERM solution should be applied to completely cover the affected area two times daily until healing is complete. Lesions generally begin to clear during the first treatment week and disappear completely after two to four weeks of treatment. In chronic or greatly hyperkeratotic lesions, more prolonged therapy may be necessary. The concomitant use of a mild keratolytic agent may be indicated especially in areas where the skin has become hyperkeratotic. Use of wet compresses prior to application of the medication aids in the healing of exudative lesions and does not interfere with the fungicidal action of TINADERM solution. Surgical debridement of dead skin and treatment of calluses is advised where necessary.

If after four weeks of therapy there has not been a progressive improvement of lesions, the diagnosis should be reconfirmed and the possible presence of resistant fungi

investigated. Mycoses complicated by bacterial infection may require additional antibiotic treatment.

PEDIATRIC DOSE:

Infants and children up to 2 years of age-Use are not recommended except under the advice and supervision of a physician. Children 2 years of age and over- usual adult and adolescent dosing regimen is followed.

CONTRAINDICATION AND WARNINGS:

Tolnaftate is contraindicated in patients with known hypersensitivity to the drug or any ingredient in the formulation. If irritation or hypersensitivity occurs, or if the patient's skin disease does not improve within 10 days, treatment should be discontinued (unless otherwise directed) and the patient should consult a clinician or podiatrist. Tolnaftate preparations are for external use only. Care should be taken to avoid contact with the eyes.

PREGNANCY AND LACTATION

Pregnancy

There are no adequate and controlled studies to date using tolnaftate in pregnant women, and the drug should be used during pregnancy only when clearly needed.

Lactation

It is not known whether tolnaftate is distributed into milk. Safe use of tolnaftate in nursing women has not been established.

ADVERSE REACTIONS: TINADERM solution is well tolerated and virtually nontoxic.

However, if irritation occurs on topical application, discontinue treatment.

Hypersensitivity reactions have been reported which can be attributed to the thimerosal content. The adverse reactions reported were: pruritus, redness, scaling, increased inflammatory response and vesicle and pustule formation.

INFORMATION FOR PATIENT

- Cleanse skin with soap and water and dry thoroughly before applying.
- Use only externally in small amounts massaged well into affected area and surrounding skin.
- Wash hands before and after applying medication.
- Avoid contact with eyes.
- Wear well-fitting, ventilated shoes and to change shoes and socks at least daily.
- Do not cover treated site with bandages unless ordered specifically by health care provider.
- Notify health care provider if there has been no apparent improvement after 10 days of treatment.
- Should not be used on nail and scalp infections unless using in addition to internal medication prescribed by health care provider.
- Store at room temperature and not in bathroom
- Report these symptoms to health care provider: persistent or severe irritation, itching, rash, stinging.

STORAGE

Store at 2° to 30°C. Keep out of reach of children.

PACKAGING:

TINADERM solution is available as a 20 ml bottle.

Marketed by:

FULFORD (INDIA) LIMITED

A subsidiary of Schering-Plough

Eureka Towers, 8th floor, Mindspace, Malad (W), Mumbai – 400064, India.

Manufactured by:

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