

Tinea-kare-Spray_Leaflet_Diecut

100w x 160h MM

Aetos

T-Derm ONCE Antifungal Spray 1% w/v

1. Name of the Medicinal Product

T-Derm ONCE Antifungal Spray 1% w/v

2. Qualitative and Quantitative Composition

Each ml contains Terbinafine Hydrochloride 1% w/v.

3. Pharmaceutical Form:

Solution.

A clear colourless solution with characteristic odour.

4. Clinical Particulars

4.1 Therapeutic indications

For the treatment of fungal skin infections such as athlete's foot (tinea pedis), jock itch (tinea cruris), ringworm (tinea corporis), pityriasis versicolor (tinea versicolor) and cutaneous candidiasis.

4.2 Posology and method of administration

Apply T-Derm ONCE Antifungal Spray 1% w/v to the affected areas once a day, for one week. Spray from a distance of 5cm to 10cm. Regular applications are essential for successful treatment. Treatment should be continued for two weeks after all clinical signs have disappeared. Attention to hygiene is important in the management of fungal diseases, particularly of the folds and the feet. If no improvement is seen after 4 weeks, diagnosis should be reviewed.

Topical administration.

4.3 Contraindications

Contraindicated in patients with known hypersensitivity to Terbinafine, or any of the ingredients in the product.

4.4 Special warnings and precautions for use

T-Derm ONCE Antifungal Spray 1% w/v should be used with caution in patients with lesions where alcohol could be irritating. For external use only.

It may be irritating to the eyes and should not be used on the face.

Avoid inhalation. In case of accidental inhalation, consult a physician if any symptoms develop or persist.

This product also contains propylene glycol, which may cause skin irritation.

4.5 Interaction with other medicinal products and other forms of interaction

Not known.

4.6 Fertility, pregnancy and breast-feeding

Usage of T-Derm ONCE Antifungal Spray 1% w/v by pregnant women and those who are trying to become pregnant, consult doctor or pharmacist for further advice. Do not use the spray during breast-feeding period.

4.7 Effects on ability to drive and use machines

Not known

4.8 Undesirable effects

Local symptoms such as pruritus, skin exfoliation, application site pain, application site irritation, pigmentation disorder, skin burning sensation, erythema and scab may occur at the site of application. These minor symptoms must be distinguished from hypersensitivity reactions such as widespread pruritus, rash, bullous eruptions and hives, which are reported in sporadic cases and require discontinuation. In case of accidental contact with the eyes Terbinafine Hydrochloride may be irritating to the eyes. In rare cases the underlying fungal infection may be aggravated. Adverse reactions are listed below by system organ class and frequency. Frequencies are defined as: very common ($\geq 1/10$); common ($\geq 1/100$ to $< 1/10$); uncommon ($\geq 1/1,000$ to $< 1/100$); rare ($\geq 1/10,000$ to $< 1/1,000$); very rare ($< 1/10,000$), or not known (cannot be estimated from available data). Within each frequency grouping, adverse reactions are presented in order of decreasing seriousness.

Immune system disorders, Not known: Hypersensitivity. **Eye disorders**, Rare: Eye irritation. **Skin and subcutaneous tissue disorders**, Common: Skin exfoliation, pruritus. Uncommon: Skin lesion, scab, skin disorder.

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pigmentation disorder, erythema, skin burning sensation. Rare: Dry skin, dermatitis contact, eczema. Not known: Rash. **General disorders and administration site conditions**, Uncommon: Pain, application site pain, application site irritation. Rare: Condition aggravated.

4.9 Overdose

The low systemic absorption of topical terbinafine renders overdosage extremely unlikely. When a large amount of T-Derm ONCE Antifungal Spray 1% w/v be inadvertently ingested, the adverse effects to be expected include headache, nausea, epigastric pain and dizziness. In case of accidental oral ingestion, the alcohol content has to be considered.

Treatment of Overdose:

If accidentally ingested, the recommended treatment of overdosage consists of eliminating the active substance, primarily by the administration of activated charcoal and giving symptomatic supportive therapy if needed.

5. Pharmacological Properties

5.1 Pharmacodynamic properties

Terbinafine Hydrochloride is an allylamine which has a broad spectrum of antifungal activity in skin fungal infections such as tinea pedis (athlete's foot), tinea cruris (jock itch) and ringworm caused by dermatophytes such as Trichophyton (e.g. T. rubrum, mentagrophytes, T. verrucosum, T. violaceum), Microsporum canis and Epidermophyton floccosum. At low concentrations, Terbinafine Hydrochloride is fungicidal against dermatophytes and moulds. The activity against yeasts is fungicidal (e.g. Pityrosporum orbiculare or Malassezia furfur) or fungistatic, depending on species. Terbinafine Hydrochloride interferes specifically with fungal sterol biosynthesis at an early step. Terbinafine Hydrochloride inhibits ergosterol synthesis by inhibiting the fungal squalene monooxygenase (squalene 2,3-epoxidase), an enzyme that is part of the fungal cell wall synthesis pathway. Terbinafine Hydrochloride does not influence the metabolism of hormones or other drugs.

5.2 Pharmacokinetic properties

Less than 5% of the dose is absorbed after topical application to humans; systemic exposure

is thus very slight. At the level of the stratum corneum, fungicidal concentrations of Terbinafine Hydrochloride can be measured up to 7 days after the last administration.

6. Pharmaceutical Particulars

6.1 List of excipients

Methylated Spirit (contains 57.24% v/v alcohol), Propylene Glycol, Fragrance and Purified Water.

6.2 Special precautions for storage

Store below 30°C. Protect from light and moisture.

Keep out of reach of children.

6.3 Nature and contents of container

The product is available in bottles of 25 ml and 30 ml.

7. Manufacturer

Syarikat Wen Ken Drug Sdn Bhd
24, Jalan Lambak, Taman Johor,
81200 Johor Bahru, Johor, Malaysia.

8. Marketing Authorisation Holder

Aetos Pharma Sdn. Bhd.
66B, Tingkat 2, Jalan Cerdas, Taman Connaught,
56000 Kuala Lumpur, Malaysia.

9. Date of Revision

24/12/2025