Summary of Product Characteristics (SmPC)

1. **Name of the Product:** TERBIZED 1% cream (Terbinafine Hydrochloride Cream)

2. **Qualitative and quantitative composition** Composition:

Terbinafine hydrochloride BP…1% w/w

Cream base……q.s.

3. Dosage form and strength

Dosage form: Cream for external use

Dosage strength: 1% w/w

4. Clinical Particulars

4.1 Therapeutic Indication

Fungal infections of the skin: mycosis of the feet (tinea pedis), inguinal epidermophytosis (tinea cruris),fungal lesions of the smooth skin of the body (tinea corporis) caused by dermatophytes Trichophyton spp., incl. Trichophyton rubrum, Trichophyton mentagrophytes, Trichophyton verrucosum, Trichophyton violaceum, Microsporum canis and Epidermophyton floccosum; - skin infections caused by yeast fungi, mainly of the genus Candida (eg C. albicans); versicolor versicolor caused by Malassezia furfur.

4.2 Posology & Method of

Administration For external use only.

For the treatment of tinea (pityriasis) versicolor, tinea corporis, tinea cruris, and tinea pedis

Terbized 1% cream is applied once daily for seven days. The affected areas should be cleansed and dried thoroughly before applying. Sufficient amounts should be applied to cover the treatment area(s) thoroughly, including the affected skin and surrounding area. Elderly patients do not need dose adjustment.

Method of Administration

Topical

4.3 Contraindications

Hypersensitivity to the components of the drug.

4.4 Warning & Precautions

Avoid getting the drug in the eyes. In case of accidental contact of the cream with the eyes, immediately rinse them with running water. When treating with Terbizid, general hygiene rules should be observed to prevent the possibility of re-infection (through underwear, shoes). Cetostearyl alcohol, which is part of the drug, can lead to local side effects (for example, contact dermatitis). If a hypersensitivity reaction occurs, treatment should be discontinued.

4.5 Drug Interactions

Potential interactions between Terbized 1%cream and other drugs have not been systematically evaluated.

4.6 Special populations

Pregnancy & Lactation

Due to the fact that clinical experience with the use of Terbizide during pregnancy is limited, the drug should be prescribed only if the expected positive effect for the mother outweighs the potential risk to the fetus. Terbinafine is excreted in breast milk, therefore, if necessary, the appointment of the drug should stop breastfeeding. Nursing mothers should avoid applying the cream to breast. The safety and efficacy of Terbized, 1%, have not been established in pediatric patients.

4.7 Effects on ability to drive and use

machines Effects on ability to drive and use

machines

4.8 Undesirable Effects

Redness at the site of application, itching or burning sensation, but these phenomena rarely lead to the need to stop treatment. Rarely: allergic reactions, the development of which requires discontinuation of treatment.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the PvERS Scheme at: www.pharmacyboardkenya.co.ke

4.9: Overdose

Overdose is unlikely, possible only with accidental ingestion.

Symptoms: headache, nausea, stomach pain and dizziness.

Treatment: the appointment of activated charcoal and gastric lavage, the use of symptomatic supportive therapy if necessary.

5. Pharmacological Properties Pharmacotherapeutic Group: Antifungal agent
Code ATC: D01AE15

5.1 Mechanism of Action/ Pharmacodynamic Properties

Terbinafine is chemically an allylamine and has a wide spectrum of antifungal activity. The mechanism of action is associated with a specific inhibition of the early stage of sterol biosynthesis in the cell membrane of fungi. This leads to a deficiency of ergosterol and to intracellular accumulation of squalene, which causes the death of fungal cells. Terbinafine acts by inhibiting squalene epoxidase in fungal cell membranes. It has fungicidal activity against dermatophytes (Trychophyton rubrum, Trychophyton mentagrophytes, Trychophyton verrucosum, Trychophyton violaceum, Trychophyton tonsurans, Microsporum canis, Epidermophyton floccosum), mold fungi (including Aspergillus, Cladosporium, Scopulariopsis brevicaulis). The action on yeast fungi of the genus Candida (mainly Candida albicans) can be fungicidal or fungistatic, depending on the type of fungus. When applied topically, terbinafine is also active against Pityrosporum orbiculare (Malassezia furfur), the causative agent of pityriasis versicolor.

5.2 Pharmacokinetic properties

When applied topically, the drug quickly penetrates the dermal layer of the skin and accumulates in the lipophilic stratum corneum. Terbinafine also penetrates the secretion of the sebaceous glands, which leads to the creation of high concentrations in the hair follicles and nails. Less than 5% of the dose is absorbed, so the absorption of terbinafine into the systemic circulation is negligible.

6. Pharmaceutical Particulars

6.1 List of excipients

1) Sodium Hydroxide
2) Benzyl Alcohol
3) Sorbitan Monostearate (Arlacel 60)
4) Cetyl Palmitate

5) Cetyl Alcohol [Ginol- 16(95%)]
6) Stearyl Alcohol (Ginol-18)
7) Polysorbate 60 (Vicapol 60)
8) Isopropyl Myristate 9) Purified Water

6.2 Incompatibilities

None known.

6.3 Shelf life

Approved Shelf life: 24 Months

6.4 Special precautions for storage

Store below 30°C in a dry place. Do not freeze.

6.5 Nature and contents of container

Cream 1% 10 g in an aluminum tube. Aluminum tube with instructions for use in a cardboard box & Cream 1% 15 g in an aluminum tube. Aluminum tube with instructions for use in a cardboard box.

6.6 Special precautions for disposal/ handling

None

7. Marketing authorization holder Agio pharmaceuticals Ltd.

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8. Marketing authorization number

H2008/19328/437

9. Date of first authorization/renewal of the authorization

2008

10. Date of revision of the text

25.07.2026