RIATEBIFINE® 250 MG TABLETS

COMPOSITION:
Tablets:
Each tablet contains Terbinafine Hydrochloride (Ph Eur) equivalent to Terbinafine 250 mg.

CLINICAL PHARMACOLOGY:
Terbinafine is an allylamine derivative which has a broad spectrum of antifungal activity. When given orally, the drug concentrates in skin, hair and nails at levels associated with fungicidal activity. At low concentrations terbinafine is fungicidal against dermatophytes, moulds and certain dimorphic fungi. Its activity against yeasts is fungicidal or fungistatic, depending on the species. Terbinafine interferes specifically with fungal ergosterol biosynthesis at an early step. This lead to a deficiency in ergosterol and to an intracellular accumulation of squalene, resulting in fungal cell death. Terbinafine acts by inhibition of squalene epoxidase in the fungal cell membrane. The enzyme squalene epoxidase is not linked to the cytochrome P450 system. When given orally, the drug concentrates in skin, hair and nails at levels associated with fungicidal activity.

INDICATIONS:
Fungal infections of the skin, hair and nails caused by Trichophyton (e.g. T. rubrum. T. mentagrophytes, T. verrucosum and T. violaceum), Microsporum canis and Epidermophyton floccosum.
- Oral RIATEBIFINE is indicated in the treatment of ringworm infections (tinea corporis, tinea cruris, and tinea pedis) where oral therapy is considered appropriate due to the site, severity or extent of the infection.
- Oral RIATEBIFINE is indicated in the treatment of onychomycosis.

CONTRAINDICATIONS:
Hypersensitivity to terbinafine or any other component of the formulation.

DRUG INTERACTIONS:
- Terbinafine may increase the levels/effects of: amphetamines, beta-blockers, dextromethorphan, fluoxetine, lidocaine, mirtazapine, nefazodone, paroxetine, risperidone, ritonavir, thioridazine, tricyclic antidepressants and venlafaxine. The effects of warfarin may be increased.
- Terbinafine may decrease the levels/effects of CYP2D6 substrates (e.g. codeine, hydrocodone, oxycodone and tramadol).

PRECAUTIONS:
- Terbinafine should not be used in patients with existing liver disease and liver function tests should be performed in all patients before starting oral therapy.
- Terbinafine should be given in reduced doses to patients with renal impairment.
- Terbinafine should be discontinued if clinical or biochemical evidence of hepatotoxicity develops; it should also be discontinued if any progressive skin rash occurs.
- Terbinafine should be used with caution in patients with psoriasis.

ADVERSE REACTIONS:
In general terbinafine will tolerated, side effects are mild to moderate and transient.
- The most common including abdominal discomfort, anorexia, nausea, diarrhoea, headache, rash and urticaria occasionally with arthralgia or myalgia.
- Less commonly taste disturbance.
- Rarely liver toxicity (including jaundice, cholestasis and hepatitis) - discontinue treatment, angioedema, dizziness. Malaise, paraesthesia, hypoesthesia, photosensitivity, serious skin reactions (including Stevens-Johnson syndrome and toxic epidermal necrolysis) - discontinue treatment if progressive skin rash.
- Very rarely psychiatric disturbances, blood disorders (including leucopenia and thrombocytopenia).

USE DURING PREGNANCY AND LACTATION:
- Terbinafine should not be used during pregnancy unless the potential benefit outweighs risk.
- Terbinafine enters breast milk, so it is not recommended for nursing women.

DOSAGE:
The duration of treatment varies according to the indication and the severity of the infection.
- **Children:** In children above 2 years of age, oral RIATEBIFINE has been found to be well tolerated.
  No data are available in children under two years of age (usually < 12 kg).

Children weighing	< 20 kg	62.5 mg	once daily
Children weighing	20 to 40 kg	125 mg	once daily
Children weighing	> 40 kg	250 mg	once daily.

- **Adults:** 250 mg once daily.
- Skin infections: recommended duration of treatment:
  - Tinea pedis (interdigital, plantar/moccasin type): 2 to 6 weeks.
  - Tinea corporis, cruris: 2 to 4 weeks.
  - Cutaneous candidiasis: 2 to 4 weeks.
  - Complete resolution of the signs and symptoms of infection may not occur until several weeks after mycological cure.
- Hair and scalp infections: recommended duration of treatment:
  -Tinea capitis: 4 weeks (it occurs primarly in children).
- Onychomycosis: for most patients the duration of successful treatment is 6-12 weeks.
  - Fingernail onychomycosis: six weeks of therapy is sufficient for fingernail infections in most cases.
  - Toenail onychomycosis: twelve weeks of therapy is sufficient for toenail infections in most cases.

Note: Some patients with poor nail outgrowth may require longer treatment. The optimal clinical effect is seen some months after mycological cure and cessation of treatment. This is related to the period required for outgrowth of healthy nail.
- **Elderly:** There is no evidence to suggest that elderly patients require different dosages or experience different side effects than younger patients. When prescribing tablets for patients in this age group, the possibility of pre-existing impairment of liver or kidney function should be considered.

STORAGE:
Store at room temperature (15-25) °C, protect from light.
Do not use the drug after the expiry date printed on the package.

PRESENTATION:
Tablets:
packs contain (7) tablets of RIATEBIFINE 250 mg.
packs contain (14) tablets of RIATEBIFINE 250 mg.
Hospital packs of RIATEBIFINE 250 mg tablets.

This is a medicament

- A medicament is a product, which affects your health, and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are experts in medicine, its benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.

Keep medicaments out of the reach of children

Council of Arab Health Ministers
Union of Arab Pharmacists

RIYADH PHARMA

Manufactured by **RIYADH PHARMA**
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