

Griso® Ultra

Griseofulvin Ultramicrosize

Description: Griseofulvin USP Ultramicrosize (**Griso® Ultra**) is an orally active antibiotic derived from a species of *Penicillium* which is used to treat tinea infections.

Mode of action: Griseofulvin (**Griso® Ultra**) has a fungistatic effect by its ability to disrupt the mitotic spindle structure of the fungal cell which arrests metaphase in cell division.

Pharmacokinetics: After oral administration, griseofulvin is deposited in the keratin precursor cells and has a greater affinity for diseased tissue. The drug is tightly bound to the new keratin which becomes highly resistant to fungal invasions. The efficiency of gastrointestinal absorption of ultramicrocrystalline griseofulvin is approximately one and one-half times that of the conventional microsize griseofulvin. This factor permits the oral intake of two-thirds as much ultramicrocrystalline griseofulvin as the microsize form. However, there is currently no evidence that this lower dose confers any significant clinical differences with regard to safety and/or efficacy.

Composition: Each Tablet Contains Griseofulvin USP Ultramicrosize 125 mg.

Indications: Griseofulvin USP Ultramicrosize (**Griso® Ultra**) is indicated for the treatment of the following tinea infections;

- tinea corporis
- onychomycosis
- tinea pedis
- tinea cruris
- tinea barbae
- tinea capitis etc.

Dosage & administration (Adults:)

- Tinea Capitis: 375 mg (as a single dose or in divided doses) 4 to 6 weeks.
- Tinea corporis: 375 mg (as a single dose or in divided doses) 2 to 4 weeks
- Tinea cruris: 375 mg (as a single dose or in divided doses)
- Tinea pedis: 375 mg (as a single dose or in divided doses) 4 to 8 weeks
- Fingernails onychomycosis: divided dose of 750 mg at least 4 months
- Toenail onychomycosis: divided dose of 750 mg at least 6 months

Pediatric Use: Approximately 7.3 mg per kg of body weight per day of ultramicrosize griseofulvin is an effective dose for most pediatric patients.

On this basis, the following dosage schedule is suggested:

16-27 kg: 125 mg to 187.5 mg daily.
over 27 kg: 187.5 mg to 375 mg daily

Children and infants 2 years of age and younger dosage has not been

established. Clinical experience with griseofulvin in children with tinea capitis indicates that a single daily dose is effective. Clinical relapse will occur if the medication is not continued until the infecting organism is eradicated.

Contraindications: This drug is contraindicated in patients with porphyria or hepatocellular failure and in individuals with a history of hypersensitivity to griseofulvin.

Side effects: Side effects reported occasionally are oral thrush, nausea, vomiting, epigastric distress, diarrhea, headache, fatigue, dizziness, insomnia, mental confusion, and impairment of performance of routine activities. Proteinuria and leukopenia have been reported rarely.

Use in pregnancy & lactation: Griseofulvin should not be prescribed to pregnant patients. If the patient becomes pregnant while taking this drug, the patient should be apprised of the potential hazard to the fetus.

Precautions: Patients on prolonged therapy with any potent medication should be under close observation. Periodic monitoring of organ system function, including renal, hepatic and hematopoietic, should be done. Since griseofulvin is derived from species of *Penicillium*, the possibility of cross sensitivity with penicillin exists; however, known penicillin-sensitive patients have been treated without difficulty. Since a photosensitivity reaction is occasionally associated with griseofulvin therapy, patients should be warned to avoid exposure to intense natural or artificial sunlight. Lupus erythematosus or lupus-like syndromes have been reported in patients receiving griseofulvin. Griseofulvin decreases the activity of warfarin-type anticoagulants so that patients receiving these drugs concomitantly may require dosage adjustment of the anticoagulant during and after griseofulvin therapy. Barbiturates usually depress griseofulvin activity and concomitant administration may require a dosage adjustment of the antifungal agent.

Drug interactions: There have been reports in the literature of possible interactions between griseofulvin and oral contraceptives. The effect of alcohol may be potentiated by griseofulvin, producing such effects as tachycardia and flush.

Over dosage: No data found.

Storage: Keep out of reach of children. Store in a dry place, below 25°C temperature and protected from light.

Packaging: Griso® Ultra Tablet: Each carton contains 14X2 **Griso® Ultra** Tablet in alu-alu blister pack.



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0915-01