Gris-PEG®

(griseofulvin ultramicrosize)

Tablets

USP

125 mg; 250 mg

DESCRIPTION: Gris-PEG® Tablets contain ultramicrosize crystals of griseofulvin, an antibiotic derived from a species of Penicillium.

Each Gris-PEG® Tablet contains:
Active Ingredients: griseofulvin ultramicrosize... 125 mg
Inactive Ingredients: colloidal silicon dioxide; lactose; magnesium stearate; methylcellulose; methylparaben; polyethylene glycol 400 and 8000; polyvinylpyrrolidone; and titanium dioxide.

OR

Active Ingredient: griseofulvin ultramicrosize... 250 mg
Inactive Ingredients: colloidal silicon dioxide; magnesium stearate; methylcellulose; methylparaben; polyethylene glycol 400 and 8000; povidone; sodium lauryl sulfate; and titanium dioxide.

ACTION: Microbiology – Griseofulvin is fungistatic with in vitro activity against various species of Microsporum, Epidermophyton and Trichophyton. It has no effect on bacteria or other genera of fungi.
Human Pharmacology – Following 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.

INDICATIONS: Gris-PEG® (griseofulvin ultramicrosize) is indicated for the treatment of the following ringworm infections: tinea corporis (ringworm of the body), tinea pedis (athlete's foot), tinea cruris (ringworm of the groin and thigh), tinea barbae (barber's itch), tinea capitis (ringworm of the scalp), and tinea unguium (onychomycosis, ringworm of the nails), when caused by one or more of the following genera of fungi: Trichophyton rubrum, Trichophyton tonsurans, Trichophyton mentagrophytes, Trichophyton interdigitalis, Trichophyton verrucosum, Trichophyton megnini, Trichophyton gallinae, Trichophyton crateriform, Trichophyton sulphureum, Trichophyton schoenleini, Microsporum audouini, Microsporum canis, Microsporum gypseum and Epidermophyton floccosum. NOTE: Prior to therapy, the type of fungi responsible for the infection should be identified. The use of the drug is not justified in minor or trivial infections which will respond to topical agents alone. Griseofulvin is not effective in the following: bacterial infections, candidiasis (moniliasis), histoplasmosis, actinomycosis, sporotrichosis, chromoblastomycosis, coccidioidomycosis, North American blastomycosis, cryptococcosis (torulosis), tinea versicolor and nocardiosis.

CONTRAINDICATIONS: Two cases of conjoined twins have been reported since 1977 in patients taking griseofulvin during the first trimester of pregnancy. 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.

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

WARNINGS: Prophylactic Usage – Safety and efficacy of griseofulvin for prophylaxis of fungal infections have not been established. Animal Toxicology - Chronic feeding of griseofulvin, at levels ranging from 0.5%-2.5% of the diet resulted in the development of liver tumors in several strains of mice, particularly in males. Smaller particle sizes result in an enhanced effect. Lower oral dosage levels have not been tested. Subcutaneous administration of relatively small doses of griseofulvin once a week during the first three weeks of life has also been reported to induce hepatomata in mice. Thyroid tumors, mostly adenomas but some carcinomas, have been reported in male rats receiving griseofulvin at levels of 2.0%, 1.0% and 0.2% of the diet, and in female rats receiving the two higher dose levels. Although studies in other animal species have not yielded evidence of tumorigenicity, these studies were not of adequate design to form a basis for conclusion in this regard. In subacute toxicity studies, orally administered griseofulvin produced hepatocellular necrosis in mice, but this has not been seen in other species. Disturbances in porphyrin metabolism have been reported in griseofulvin-treated laboratory animals. Griseofulvin has been reported to have a colchicine-like effect on mitosis and cocarcinogenicity with methylcholanthrene in cutaneous tumor induction in laboratory animals. Usage in Pregnancy – See CONTRAINDICATIONS section. Animal Reproduction Studies – It has been reported in the literature that griseofulvin was found to be embryotoxic and teratogenic on oral administration to pregnant rats. Pups with abnormalities have been reported in the litters of a few bitches treated with griseofulvin. Suppression of spermatogenesis has been reported to occur in rats, but investigation in man failed to confirm this.

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. 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.

ADVERSE REACTIONS: When adverse reactions occur, they are most commonly of the hypersensitivity type such as skin rashes, urticaria, erythema multiforme-like drug reactions, and rarely, angioneurotic edema, and may necessitate withdrawal of therapy and appropriate countermeasures. Paresthesias of the hands and feet have been reported rarely after extended therapy. Other 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. Administration of the drug should be discontinued if granulocytopenia occurs. When rare, serious reactions occur with griseofulvin, they are usually associated with high dosages, long periods of therapy, or both.

DOSAGE AND ADMINISTRATION: Accurate diagnosis of the infecting organism is essential. Identification should be made either by direct microscopic examination of a mounting of infected tissue in a solution of potassium hydroxide or by culture on an appropriate medium. Medication must be continued until the infecting organism is completely eradicated as indicated by appropriate clinical or laboratory examination. Representative treatment periods are tinea capitis, 4 to 6 weeks; tinea corporis, 2 to 4 weeks; tinea pedis, 4 to 8 weeks; tinea unguium – depending on rate of growth – fingernails, at least 4 months; toenails, at least 6 months.

General measures in regard to hygiene should be observed to control sources of infection or reinfection. Concomitant use of appropriate topical agents is usually required, particularly in treatment of tinea pedis. In some forms of athlete's foot, yeast and bacteria may be involved as well as fungi. Griseofulvin will not eradicate the bacterial or monilial infection.

Adults: Daily administration of 375 mg (as a single dose or in divided doses) will give a satisfactory response in most patients with tinea corporis, tinea cruris, and tinea capitis. For those fungal infections more difficult to eradicate, such as tinea pedis and tinea unguium, a divided dose of 750 mg is recommended.

Pediatric Use: Approximately 3.3 mg per pound 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: Children weighing 35-60 pounds – 125 mg to 187.5 mg daily. Pediatric patients weighing over 60 pounds – 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.

HOW SUPPLIED: Gris-PEG® (griseofulvin ultramicrosize) Tablets, 125 mg, white, scored, elliptical-shaped, embossed "Gris-PEG®" on one side and "125" on the other. Gris-PEG® (griseofulvin ultramicrosize) Tablets, 250 mg, white, scored, capsule-shaped, embossed "Gris-PEG®" on one side and "250" on the other. The 125 mg strength is available in bottles of 100 (NDC 0023-0763-04). The 250 mg strength is available in bottles of 100 (NDC 0023-0773-04) and 500 (NDC 0023-0773-50). Both strengths are film-coated.

CAUTION: Federal (U.S.A.) law prohibits dispensing without prescription.

STORAGE: Store Gris-PEG® tablets at controlled room temperature 15°-30°C (59°-86°F) in tight, light-resistant containers.

Manufactured for
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