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FULVICIN-U/F® Tablets brand of griseofulvin (microsize) tablets, U.S.P. CLINICAL CONSIDERATIONS—

INDICATIONS Griseofulvin is indicated for the treatment of ringworm infections of the skin, hair, and nails, namely: *Tinea corporis*, *Tinea pedis*, *Tinea cruris*, *Tinea barbae*, *Tinea capitis*, *Tinea unguium* (onychomycosis) 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 schoenleinii*, *Microsporium audouinii*, *Microsporium canis*, *Microsporium gypseum*, *Epidermophyton floccosum*.

NOTE: Prior to therapy, the type of fungi responsible for the infection should be identified. The use of this 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*, Nocardiosis.

CONTRAINDICATIONS This drug is contraindicated in patients with porphyria, hepatocellular failure, and in individuals with a history of sensitivity 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. Although studies in other animal species have not yielded evidence of tumorigenicity, these studies were not of adequate design to form a basis for conclusions 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: The safety of this drug during pregnancy has not been established.

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. Additional animal reproduction studies are in progress.

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 functions, 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. Should a photosensitivity reaction occur, lupus erythematosus may be aggravated.

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.

ADVERSE REACTIONS When adverse reactions occur, they are most commonly of the hypersensitivity type, such as skin rashes, urticaria, and rarely, angioneurotic edema, and may necessitate withdrawal of therapy and appropriate counter-measures. 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.

AVAILABLE in 125 mg., 250 mg., and 500 mg. scored tablets.

010 AUGUST 1973
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