ULTRAMICROSIZE GRISEOFULVIN- ultramicrosize griseofulvin tablet
Chartwell RX, LLC

Ultramicrosize Griseofulvin Tablets, USP

DESCRIPTION

Ultramicrosize Griseofulvin Tablets, USP contain ultramicrosize crystals of griseofulvin, an antibiotic derived from a species of *Penicillium*. Griseofulvin crystals are partly dissolved in polyethylene glycol 8000 and partly dispersed throughout the label matrix.

Each Ultramicrosize Griseofulvin Tablet, USP contains 165 mg ultramicrosize griseofulvin, USP.

The inactive ingredients for Ultramicrosize Griseofulvin Tablets, USP include: corn starch, lactose anhydrous, magnesium stearate, polyethylene glycol 8000, and sodium lauryl sulfate.

ACTIONS Microbiology Griseofulvin is fungistatic with *in vitro*activity against various species of *Microsporum, Epidermophyton*, and *Trichophyton*. It has no effect on bacteria or on 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

Ultramicrosize griseofulvin tablets are 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 interdigitale, Trichophyton verrucosum, Trichophyton megninii, Trichophyton gallinae, Trichophyton crateriforme, Trichophyton sulphureum, Trichophyton schoenieinii, 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 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, and nocardiosis.

CONTRAINDICATIONS

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

Rare cases of conjoined twins have been reported in patients taking griseofulvin during the first trimester of pregnancy. Griseofulvin should not be prescribed to pregnant patients or to women contemplating pregnancy.

WARNINGS

*Prophylactic Usage:*Safety and efficacy of griseofulvin for prophylaxis of fungal infections have not been established.

Since griseofulvin has demonstrated harmful effects *in vitro*on the genotype in bacteria, plants, and fungi, males should wait at least 6 months after completing griseofulvin therapy before fathering a child. Females should avoid risk of pregnancy while receiving griseofulvin therapy.

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 3 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 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.

Griseofulvin interferes with chromosomal distribution during cell division, causing aneuploidy in plant and mammalian cells. These effects have been demonstrated *in vitro*at concentrations that may be achieved in the serum with the recommended therapeutic dosage.

*Usage in Pregnancy:*Griseofulvin should not be prescribed to pregnant patients or to women contemplating pregnancy (see **CONTRAINDICATIONS**).

*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, or exacerbation of existing lupus, have been reported in patients receiving griseofulvin.

*Drug Interactions:*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.

The effects of alcohol may be potentiated by griseofulvin, producing such effects as tachycardia and flush.

Griseofulvin may potentiate an increase in hepatic enzymes that metabolize estrogens at an increased rate, including the estrogen component of oral contraceptives, thereby causing possible decreased contraceptive effects and menstrual irregularities.

ADVERSE REACTIONS

When adverse reactions occur, they are most commonly of the hypersensitivity type, such as skin rashes and urticaria, and rarely, angioneurotic edema and epidermal necrolysis (Lyell’s syndrome), 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, nephrosis, leukopenia, hepatic toxicity, GI bleeding, and menstrual irregularities 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, yeasts and bacteria may be involved as well as fungi. Griseofulvin will not eradicate the bacterial or monilial infection.

Adults: Daily administration of 330 mg (as a single dose or in divided amounts) will give a satisfactory response in most patients with tinea corporis, tinea cruris, and tinea capitis. For those fungus infections more difficult to eradicate, such as tinea pedis and tinea unguium, a divided daily dosage of 660 mg is recommended.

Children: Approximately 3.3 mg per pound of body weight per day is an effective dose for most children. On this basis, the following dosage schedule is suggested: Children weighing 30 to 50 pounds- 82.5 mg to 165 mg daily. Children weighing over 50 pounds – 165 mg to 330 mg daily.

Children 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

Ultramicrosize Griseofulvin Tablets, USP 165 mg, off-white, oval shaped, scored tablets debossed with " **C**" bisect " **E**" on one side and " **269**" on the other side; bottle of 30 (NDC 62135-501-30).

Store at 20° to 25°C (68° to 77°F). [see USP Controlled Room Temperature].

Manufactured for:

Chartwell RX, LLC.

Congers, NY 10920

L72564

Rev. 02/2025

PRINCIPAL DISPLAY PANEL

Ultramicrosize Griseofulvin Tablets, USP 165 mg- NDC 62135-501-30 - 30s Tabs Bottle Label

ULTRAMICROSIZE GRISEOFULVIN

ultramicrosize griseofulvin tablet

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:62135-501
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
GRISEOFULVIN (UNII: 32HRV3E3D5) (GRISEOFULVIN - UNII:32HRV3E3D5)	GRISEOFULVIN	165 mg

Inactive Ingredients	
Ingredient Name	**Strength**
STARCH, CORN (UNII: O8232NY3SJ)	
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLYETHYLENE GLYCOL 8000 (UNII: Q662QK8M3B)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	

Product Characteristics			
Color	white (off White)	**Score**	2 pieces
Shape	OVAL	**Size**	15mm
Flavor		**Imprint Code**	C;E;269
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62135-501-30	30 in 1 BOTTLE; Type 0: Not a Combination Product	01/30/2025	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA061996	04/06/1982	

Labeler - Chartwell RX, LLC (079394054)

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