GRISEOFULVIN- griseofulvin (microsize) suspension
Chartwell RX, LLC.

Griseofulvin Oral Suspension, USP (microsize)

125 mg/5 mL

Rx Only

Description

Griseofulvin is an antibiotic derived from a species of *Penicillium.* Each 5 mL of Griseofulvin Oral Suspension, USP contains 125 mg of griseofulvin (microsize) and also contains alcohol (0.2%), docusate sodium, FD&C Red No. 40, FD&C Yellow No. 6, magnesium aluminum silicate, menthol, methylparaben, orange cream flavors, propylene glycol, propylparaben, purified water, saccharin sodium, simethicone emulsion, sodium alginate and sucrose.

Clinical Pharmacology

Griseofulvin Oral Suspension, USP acts systemically to inhibit the growth of *Trichophyton, Microsporum,* and *Epidermophyton* genera of fungi. Fungistatic amounts are deposited in the keratin, which is gradually exfoliated and replaced by noninfected tissue.

Griseofulvin absorption from the gastrointestinal tract varies considerably among individuals, mainly because of insolubility of the drug in aqueous media of the upper G.I. tract. The peak serum level found in fasting adults given 0.5 gm occurs at about four hours and ranges between 0.5 and 2.0 mcg/mL.

It should be noted that some individuals are consistently "poor absorbers" and tend to attain lower blood levels at all times. This may explain unsatisfactory therapeutic results in some patients. Better blood levels can probably be attained in most patients if griseofulvin is administered after a meal with a high fat content.

Indications and Usage

Major indications for Griseofulvin Oral Suspension, USP are:

Tinea capitis (ringworm of the scalp)
Tinea corporis (ringworm of the body)
Tinea pedis (athlete's foot)
Tinea unguium (onychomycosis; ringworm of the nails)
Tinea cruris (ringworm of the thigh)
Tinea barbae (barber’s itch)

Griseofulvin Oral Suspension, USP inhibits the growth of those genera of fungi that

commonly cause ringworm infections of the hair, skin, and nails, such as:
Trichophyton rubrum
Trichophyton tonsurans
Trichophyton mentagrophytes
Trichophyton interdigitalis
Trichophyton verrucosum
Trichophyton sulphureum
Trichophyton schoenleini
Microsporum audouini
Microsporum canis
Microsporum gypseum
Epidermophyton floccosum
Trichophyton megnini
Trichophyton gallinae
Trichophyton crateriform

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 antifungal agents alone.

It is *not* effective in:
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 hypersensitivity to griseofulvin.

Two 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.

Warnings

Prophylactic Usage: Safety and efficacy of prophylactic use of this drug has not been established.

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.

Reports of animal studies in the Soviet literature state that a griseofulvin preparation was found to be embryotoxic and teratogenic on oral administration to pregnant Wistar rats. Rat reproduction studies done in the United States and Great Britain were inconclusive in this regard. Pups with abnormalities have been reported in the litters of a few bitches treated with griseofulvin. Because the potential for adverse effects on the human fetus cannot be ruled out, additional contraceptive precautions should be taken during treatment with griseofulvin and for a month after termination of treatment. Griseofulvin Oral Suspension, USP should not be prescribed to women intending to become pregnant within one month following cessation of therapy.

Suppression of spermatogenesis has been reported to occur in rats but investigation in man failed to confirm this. 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.

Since griseofulvin has demonstrated harmful effects *in vitro* on the genotype in bacteria, plants, and fungi, males should wait at least six months after completing griseofulvin therapy before fathering a child.

Precautions

Patients on prolonged therapy with any potent medication should be under close observation. Periodic monitoring of organ system function, including renal, hepatic and hemopoietic, should be done.

Since griseofulvin is derived from species of penicillin, 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.

Drug Interactions: Patients on warfarin-type anticoagulant therapy may require dosage adjustment of the anticoagulant during and after griseofulvin therapy. Concomitant use of barbiturates usually depresses griseofulvin activity and may necessitate raising the dosage.

The concomitant administration of griseofulvin has been reported to reduce the efficacy of oral contraceptives and to increase the incidence of breakthrough bleeding.

Adverse Reactions

When adverse reactions occur, they are most commonly of the hypersensitivity type such as skin rashes, urticaria and rarely, angioneurotic edema or erythema multiforme-like drug reaction, 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 since in some forms of athlete's foot, yeasts and bacteria may be involved. Griseofulvin will not eradicate the bacterial or monilial infection.

Adults: A daily dose of 500 mg 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 daily dose of 1 gram is recommended.

Children: Approximately 5 mg per pound of body weight per day is an effective dose for most children. On this basis the following dosage schedule for children is suggested:

Children weighing 30 to 50 pounds - 125 mg to 250 mg daily.
Children weighing over 50 pounds - 250 mg to 500 mg daily.

How Supplied

Griseofulvin Oral Suspension, USP (microsize) 125 mg per 5 mL is available as follows:
4 fl oz (120 mL) bottle (NDC 62135-968-41)

Dispense Griseofulvin Oral Suspension, USP in a tight, light-resistant container as defined in the USP.

STORAGE

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

Manufactured by:
Chartwell Pharmaceuticals, LLC.
Congers, NY 10920

Manufactured for:
Chartwell RX, LLC.
Congers, NY 10920

L70567 Rev: 08/2021

PRINCIPAL DISPLAY PANEL

Griseofulvin Oral Suspension, USP (microsize) 125 mg/5 mL - NDC 62135-968-41 - Label

GRISEOFULVIN

griseofulvin (microsize) suspension

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:62135-968
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
GRISEOFULVIN (UNII: 32HRV3E3D5) (GRISEOFULVIN - UNII:32HRV3E3D5)	GRISEOFULVIN	125 mg in 5 mL

Inactive Ingredients

Ingredient Name	Strength
ALCOHOL (UNII: 3K9958V90M)	
DOCUSATE SODIUM (UNII: F05Q2T2JA0)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
MAGNESIUM ALUMINUM SILICATE (UNII: 6M3P64V0NC)	
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SODIUM ALGINATE (UNII: C269C4G2ZQ)	
SUCROSE (UNII: C151H8M554)	

Product Characteristics

Color	orange	**Score**	
Shape		**Size**	
Flavor	ORANGE (Orange, cream)	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62135-968-41	120 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/26/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA065200	03/02/2005	

Labeler - Chartwell RX, LLC. (079394054)

Establishment

Name	Address	ID/FEI	Business Operations
Chartwell Pharmaceuticals Congers, LLC.		118673447	analysis(62135-968) , label(62135-968) , manufacture(62135-968) , pack(62135-968)

Revised: 10/2024 Chartwell RX, LLC.