GRISEOFULVIIN (MICROSIZE)- griseofulvin (microsize) suspension
Rebel Distributors Corp

GRISEOFULVIN ORAL SUSPENSION (microsize) USP, 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%, artificial orange vanilla flavor, docusate sodium, FD&C Red No. 40, FD&C Yellow No. 6, magnesium aluminium silicate, menthol, methylparaben, propylene glycol, propylparaben, saccharin sodium, simethicone emulsion, sodium alginate, sucrose, and purified water.

CLINICAL PHARMACOLOGY

Griseofulvin 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 are:

Griseofulvin inhibits the growth of those genera of fungi that commonly cause ringworm infections of the hair, skin, and nails, such as:

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:

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 have been inconclusive in this regard, and additional animal reproduction studies are underway. 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 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:

HOW SUPPLIED

Griseofulvin Oral Suspension USP 125 mg per 5 mL is an orange-vanilla flavored suspension available in bottles of 4 fl oz (120 mL).

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

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

Manufactured by:

Actavis Mid Atlantic LLC

1877 Kawai Road

Lincolnton, NC 28092 USA

Form No. 0013

Rev. 7/07

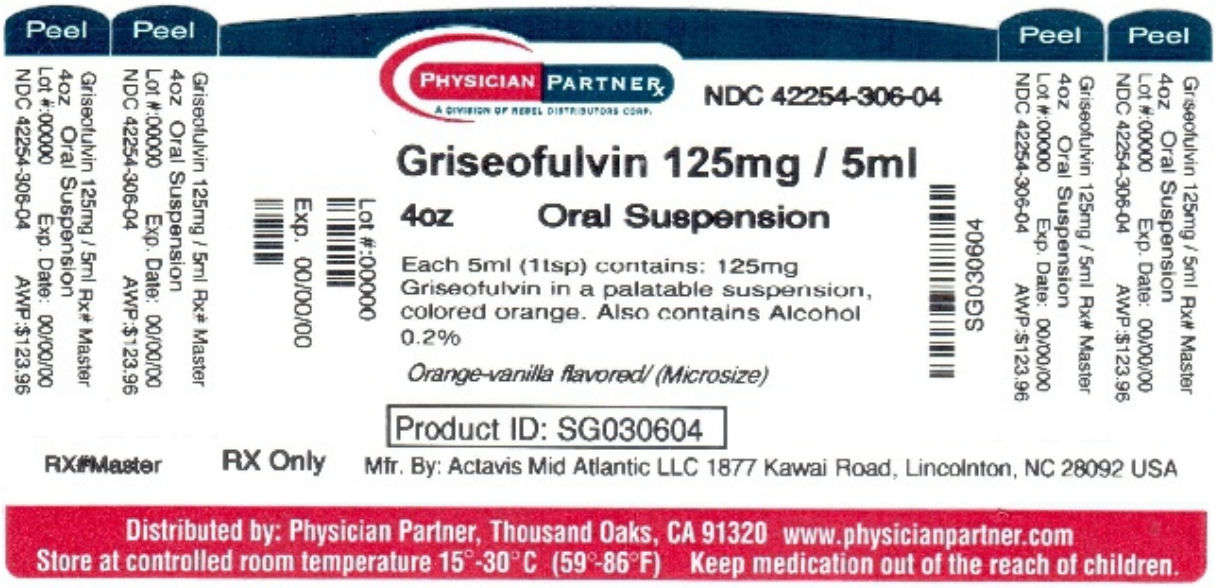
VC2965

Repackaged by:

Rebel Distributors Corp.

Thousand Oaks, CA 91320

PRINCIPAL DISPLAY PANEL



GRISEOFULVIIN (MICROSIZE)

griseofulvin (microsize) suspension

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:42254-306(NDC:0472-0013)
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 (UNII: L7T10EIP3A)	

METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SODIUM ALGINATE (UNII: C269C4G2ZQ)	
SUCROSE (UNII: C151H8M554)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:42254-306-04	120 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA065394	07/26/2007	

Labeler - Rebel Distributors Corp (118802834)

Registrant - PSS World Medical, Inc. (101822862)

Establishment

Name	Address	ID/FEI	Business Operations
PSS World Medical, Inc.		791528623	REPACK(42254-306)

Establishment

Name	Address	ID/FEI	Business Operations
STAT RX USA LLC		786036330	REPACK(42254-306)

Establishment

Name	Address	ID/FEI	Business Operations
Dispensing Solutions, Inc.		066070785	RELABEL(42254-306) , REPACK(42254-306)

Establishment

Name	Address	ID/FEI	Business Operations
SCRIPT PAK		964420108	RELABEL(42254-306) , REPACK(42254-306)

Establishment

Name	Address	ID/FEI	Business Operations
Keltman Pharmaceuticals, Inc.		362861077	REPACK(42254-306)

Establishment

Name	Address	ID/FEI	Business Operations
Rebel Distirbutors Corp.		118802834	RELABEL(42254-306) , REPACK(42254-306)