



AGOG Pharma Ltd.



(WHO - GMP CERTIFIED - GOVT RECOGNISED EXPORT HOUSE)

Regd. Office & Factory : Plot No. 33, Sector II, The Vasai Taluka Industrial Co-op. Estate Ltd. Gaurai-pada, Vasai (E), Dist. Thane - 401 208. INDIA.
Tel. : 95250 - 2455801 / 2452714 / 2453525 • Fax : 95250 - 2452074 (0091 - 250 - 2452074) • Email : agog@vsnl.net & agogpharma@rediffmail.com

LEAFLET

AGOFULVIN - 125 (Griseofulvin Tablets BP 125 mg)

COMPOSITION:

Each uncoated tablet contains:
Griseofulvin BP 125 mg
Excipients q.s.

CLINICAL PHARMACOLOGY:

Griseofulvin is a fungistatic antibiotic that inhibits fungal cell division by disruption of the mitotic spindle structure. It may also interfere with DNA production. It is active against the common dermatophytes, including some species of Epidermophyton, Microsporum, or Trichophyton.

PHARMACOKINETICS:

Absorption of Griseofulvin from the gastro-intestinal tract is variable and incomplete, but is enhanced by reducing the particle size and by administration with a fatty meal. Griseofulvin is about 84% bound to plasma proteins. Concentrations of 12 to 25µg per g are maintained in the skin during long-term administration, while concurrent plasma concentrations remain at about 1 to 2µg per mL. Griseofulvin has an elimination half-life of about 9 to 24 hours, and is metabolised by the liver mainly to 6-desmethylgriseofulvin and its glucuronide conjugate which are excreted in the urine. A large amount of a dose of Griseofulvin of reduced particle size appears unchanged in the faeces; less than 1% is excreted unchanged in the urine; some is excreted in the sweat.

USES:

Griseofulvin is an antifungal administered by mouth in the treatment of dermatophyte infections. It is generally given for such infections that involve the scalp, hair, nails, and skin and which do not respond to topical treatment; infections of the soles of the feet, the palms of the hands, and the nails respond slowly.

DOSAGE AND ADMINISTRATION:

The usual dose of Griseofulvin is 0.5 to 1 g daily in single or divided doses; children may be given 10mg per kg body-weight daily. The duration of treatment depends on the thickness of the keratin layer: 2 to 8 weeks for the infections of the hair and skin, up to 6 months for infections of the finger nails, and 12 months or more for infections of toenails. The dose should be given with or after meals.

CONTRA-INDICATIONS AND WARNINGS:

Precautions:

Griseofulvin is contra-indicated in patients with severe liver disease or systemic lupus erythematosus. It is contra-indicated in pregnancy and women should not

become pregnant during, or within 1 month of stopping, Griseofulvin treatment. Since Griseofulvin may reduce the effectiveness of oral contraceptives, additional contraceptive precautions should be taken during this time. Data from in-vitro and in-vivo studies using mammalian cells which demonstrated aneuploidy have led to the warning that men receiving griseofulvin should not father children within 6 months of treatment. Griseofulvin may impair the ability to drive or operate machinery, and has been reported to enhance the effects of alcohol.

Adverse Effects:

Adverse effects are usually mild and transient and consist of headache, skin rashes and urticaria, dry mouth, an altered sensation of taste, and gastrointestinal disturbances. Angioedema, erythema multiforme, toxic epidermal necrolysis, proteinuria, leucopenia and other blood dyscrasias, oral candidiasis, peripheral neuropathy, photosensitisation, and severe headache have been reported occasionally. Depression, confusion, dizziness, insomnia, and fatigue have also been reported.

Interactions:

Phenobarbital has been reported to decrease the gastrointestinal absorption of griseofulvin.

The blood level, and hence efficacy of griseofulvin may also be impaired as a result of concurrent administration of substances such as phenylbutazone and sedative and hypnotic drugs which induce metabolising enzymes. Griseofulvin may increase the rate of metabolism and diminish the effects of some drugs such as coumarin anticoagulants and oral contraceptives. Griseofulvin has also been reported to reduce plasma concentrations of salicylate in a patient taking aspirin. Griseofulvin may enhance the effects of alcohol.

Storage:

Store under normal storage conditions (15°C to 30°C).
Keep all medicines out of reach of children
Protect from light.

Presentation:

Jar pack of 1000 Tablets.
Jar Pack of 100 Tablets
Blister pack of 10 x 10 Tablets.



Manufactured in India by:

AGOG PHARMA LTD.

Plot No. 33, Sector II, The Vasai Taluka Ind.
Co-op. Estate Ltd., Vasai (E), Dist. Thane, INDIA.

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1.5.3 Patient information leaflet (PIL)

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