

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. Gauraipada, 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-250 TABLETS

(Griseofulvin Tablets BP 250 mg)

Each uncoated tablet contains: Griseofulvin BP 250 mg Excipients .

Category: Antifungal drug

Mechanism:

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. Clearing such infections will get rid of symptoms such as itching, red/peeling/scaly skin, and discolored nails. This medication works by stopping the growth of fungi.

Indication: Griseofulvin is indicated for the treatment of ringworm infection of namely-

• Tinea Capitis (ringworm of scalp)

- Tinea barbac (fungal infection of beard caused by T. faviforme, T. metagrophytes and M. Canis).

 Tinea pedis and Tinea manas (ringworm of the feet and hands.)
- Tinea cruris and tinea corporis (ringworm of the groin and the body)
 Onychomycosis (Fungus infection of the nails)

Dosage & Administration:

<2 years old: Safety and efficacy not established. Microsize: 10-20 mg/kg/day orally in two divided doses. Max: 1 gm/day. Ultramicrosize: 5-15 mg/kg/day orally in two divided doses. Max: 750

Give for 4-6 months for onychomycosis, for 4-8 weeks for tinea pedis, for 2-6 weeks for tinea cruris, for 4-6 weeks for tinea capitis. for 2-4 weeks for tinea corporis, and >6 weeks for tinea barbae.

Contraindications:

This drug is contraindicated in patients with porphyria, hepatocellular failure and in individuals with a history of hypersensitivity to griseofulvin. Males should not father children within 6 months of treatment.

Drug Interactions:

Warfarin-type anticoagulants: Griseofulvin decreases the activity, dose

adjustment of the anticoagulant during and after griseofulvin therapy may be required.

Warnings and precautions:

Griseofulvin can cause a severe allergic reaction. Symptoms can include:

trouble breathing

swelling of your throat or tongue

Don't take this drug again if you've ever had an allergic reaction to it.

Taking it again could be fatal (cause death).

This drug may make you more sensitive to the effects of alcohol. You should not drink alcohol while you're taking this drug.

Don't take this drug-

- For people with porphyria (a genetic blood disease)
- For people with liver problems
- · For people with lupus
- For pregnant women
- For women who are breastfeeding

Adverse Effect:

Hypersensitivity reactions (urticaria, skin rashes, epidermal necrolysis and angioneurotic edema), paresthesias of the hands and feet, diarrhea, oral thrush, headache, fatigue, nausea, vomiting, epigastric distress, dizziness insomnia, mental confusion, nephrosis, proteinuria, hepatic toxicity, leukopenia, GI bleeding and menstrual irregularities.

Store under normal storage condition (15°C to 30°C). Protect from light.

Keep all medicines out of reach of children.

PRASENTATION:

A Bulk pack of 100's & 1000's Tablets. Blister Pack of 10 x 10 Tablets



Manufactured in India by:

AGOG PHARMA LTD.

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



Pharma Ltd.





Regd. Office & Factory: Plot No. 33, Sector II, The Vasai Taluka Industrial Co-op. Estate Ltd. Gauraipada, 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

1.5.3 Patient information leaflet (PIL)

AGOFULVIN-250 TABLETS

(Griseofulvin Tablets BP 250 mg)

Composition: Each uncoated tablet contains: Griseofulvin BP 250 mg Excipients ...

Category: Antifungal drug

Mechanism:

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. Clearing such infections will get rid of symptoms such as itching, red/peeling/scaly skin, and discolored nails. This medication works by stopping the growth of fungi.

Indication: Griseofulvin is indicated for the treatment of ringworm infection of namely-

Tinea Capitis (ringworm of scalp)

Tinea barbac (fungal infection of beard caused by T. faviforme, T. metagrophytes and M. Canis).

Tinea pedis and Tinea manas (ringworm of the feet and hands.
 Tinea cruris and tinea corporis (ringworm of the groin and the body)

Onychomycosis (Fungus infection of the nails)

Dosage & Administration:

<2 years old: Safety and efficacy not established.</p>

Microsize: 10-20 mg/kg/day orally in two divided doses. Max: 1 gm/day. Ultramicrosize: 5-15 mg/kg/day orally in two divided doses. Max: 750 mg/day.

Give for 4-6 months for onychomycosis, for 4-8 weeks for tinea pedis, for 2-6 weeks for tinea cruris, for 4-6 weeks for tinea capitis. for 2-4 weeks for tinea corporis, and >6 weeks for tinea barbae.

Contraindications:

This drug is contraindicated in patients with porphyria, hepatocellular failure and in individuals with a history of hypersensitivity to griseofulvin. Males should not father children within 6 months of treatment.

Warfarin-type anticoagulants: Griseofulvin decreases the activity, dose

adjustment of the anticoagulant during and after griseofulvin therapy may be required.

Warnings and precautions:

Griseofulvin can cause a severe allergic reaction. Symptoms can include:

trouble breathing
 swelling of your throat or tongue

Don't take this drug again if you've ever had an allergic reaction to it.

Taking it again could be fatal (cause death).

This drug may make you more sensitive to the effects of alcohol. You should not drink alcohol while you're taking this drug.

Don't take this drug-

For people with porphyria (a genetic blood disease)

For people with liver problems
For people with lupus

For pregnant women

For women who are breastfeeding

Adverse Effect:

Hypersensitivity reactions (urticaria, skin rashes, epidermal necrolysis and angioneurotic edema), paresthesias of the hands and feet, diarrhea, oral thrush, headache, fatigue, nausea, vomiting, epigastric distress, dizziness insomnia, mental confusion, nephrosis, proteinuria, hepatic toxicity, leukopenia, GI bleeding and menstrual irregularities.

STORAGE:

Store under normal storage condition (15°C to 30°C). Protect from light.

Keep all medicines out of reach of children.

PRASENTATION:

A Bulk pack of 100's & 1000's Tablets. Blister Pack of 10 x 10 Tablets



Manufactured in India by:

AGOG PHARMA LTD.

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