GRISEOFULVINA 500 mg

Comprimidos BP

Composition:
Each uncoated tablet contains:
Griseofulvin BP 500 mg
Excipients q.s.

Indications: Treatment of fungal infections of the skin, scalp, hair, or nails where topical therapy is considered inadequate or has failed. When griseofulvin is administered orally for the systemic treatment of fungal infections, it enables newly formed keratin in the skin, hair, and nails to resist fungal attack. As the new keratin grows out, the old, infected keratin is shed. Griseofulvin is effective against dermatophytes that cause ringworm (tinea), including *Microsporum canis* and *T. verrucosum*. Griseofulvin is not effective against infections caused by *Candida albicans*, *Aspergillus* species, *Malassezia furfur* (pityriasis versicolor), or *Nocardia*.

Dosage: Doses should be taken after meals; otherwise, absorption is likely to be inadequate.
Adults: 500 to 1000 mg daily, but not less than 10 mg/kg of body weight per day. A single daily dose is often satisfactory, but divided doses may be more effective in patients who respond poorly.
Children: 10 mg/kg (5 mg/lb) of body weight daily in divided doses.

Treatment duration: This depends on the thickness of the keratin at the infection site. For hair or skin, it takes at least four weeks, whereas six to twelve months of treatment may be required for fingernails or toenails. Therapy should continue for at least two weeks after all signs of infection have disappeared.

Contraindications: Griseofulvin may aggravate liver disease, and liver function should be monitored in such conditions. Systemic lupus erythematosus: griseofulvin has been reported to exacerbate the condition.

Special warnings and precautions for use: None.

Interactions with other medicines and other forms of interaction: Griseofulvin may reduce blood levels and, consequently, the efficacy of certain medicines metabolized by cytochrome P450 3A4. These include oral contraceptives, coumarin anticoagulants, and cyclosporine. Griseofulvin absorption is inhibited when phenobarbital is taken concomitantly. Blood levels and, consequently, the efficacy of griseofulvin may also be impaired by the simultaneous administration of substances such as phenylbutazone and sedative or hypnotic drugs that induce metabolizing enzymes. Patients should be advised that an enhancement of the effects of alcohol has been reported.

Pregnancy and breastfeeding: Griseofulvin is teratogenic in animals, and some cases of human fetal abnormalities have been reported. Therefore, griseofulvin should not be used during pregnancy or by women intending to become pregnant within one month of stopping treatment. Men should not father children for six months after treatment with griseofulvin. It is not known whether griseofulvin is excreted in human milk. Safety in nursing infants has not been established.

Adverse effects: Diarrhea, nausea, and vomiting are common side effects. Headache and gastric discomfort sometimes occur but usually resolve as treatment continues. In rare instances, urticarial reactions, skin rashes, and the precipitation of systemic lupus erythematosus have been reported. Toxic epidermal necrolysis and erythema multiforme have been reported. There have been reports of central nervous system effects, such as confusion, dizziness, impaired coordination, and peripheral neuropathy. Photosensitivity reactions may occur upon exposure to intense natural or artificial sunlight. Drowsiness has been reported.

Overdose: Treatment is unlikely to be required in cases of acute overdose.

Storage: Store below 30°C in a dry place; protect from light.

Keep medicines out of the reach of children.

Presentation: Blister pack of 10 tablets.

Manufactured by:
US Pharma®
(INDIA) Private Limited
Pioneering Excellence. Redefining Quality.
www.uspharma.in