1. Name of the Medicinal Product

1.1 (Invented) Name of the Medicinal Product

Emba Fesovin 500mg

1.2. Strength

500 mg

1.3. Pharmaceutical Dosage Form

Solid Oral Dosage Form: Tablets

2. Qualitative And Quantitative Composition

Qualitative Declaration

Emba Fesovin contains Griseofulvin BP.

Quantitative Declaration

Each uncoated tablets contains:

Griseofulvin BP	500mg
Excipients	q.s.

3. Pharmaceutical Form

Tablets

4. Clinical Particulars

4.1 Therapeutic Indications

For the treatment of ringworm infections of the skin, hair, and nails, namely: tinea corporis, tinea pedis, tinea cruris, tinea barbae, cradle cap or other conditions caused by Trichophyton or Microsporum fungi

4.2 Posology and Method of Administration

Oral

Dermatophytosis

Adult: 0.5-1 g daily in single or divided doses for 2-8 weeks in hair and skin infections, 6 months in fingernail infections and 12 months or more for toenail infections.

Child: 10 mg/kg daily

Method of administration

Oral

4.3 The Preparation for Use:

Not Applicable

4.4 Contraindications

Hypersensitivity to Griseofulvin or any of the excipients, pregnancy, porphyria, or hepatocellular failure

4.5 Special Warning and Precautions for Use

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 colchicines-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. GRIFULVIN V (Griseofulvin microsize) 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.

4.6 Interaction with Other Medicinal Products and Other Forms of Interaction

Phenobarbitone has been reported to decrease the gastrointestinal absorption of Griseofulvin. Griseofulvin may increase the rate of metabolism and diminish the side effects of some drugs such as coumarin anticoagulants and oral contraceptives. Use of an alternate or additional means of contraception if taking estrogen-containing oral contraceptives concurrently with Griseofulvin and for one month after stopping Griseofulvin therapy is advisable. Griseofulvin has also been reported to reduce the plasma concentrations of salicylate in patients taking aspirin.

Since Griseofulvin is derived from a species of Penicillum, it is theoretically possible that patients intolerant to penicillin's or penicillamine may be intolerant of Griseofulvin also. However, cross-sensitivity between Griseofulvin and penicillin or penicillamine has not been clinically substantiated. In addition penicillin-sensitive patients have received Griseofulvin without difficulty

4.7 Pregnancy and Lactation

Pregnancy

Griseofulvin is not recommended during pregnancy and lactation.

4.8 Effects on Ability to Drive and Use Machines

None

4.9 Undesirable Effects

Oral thrush; GI distress, taste perversion; dizziness, confusion, headache, depression, insomnia, fatigue; peripheral neuritis, photosensitivity; skin rashes, urticaria, erythema multiforme; leucopenia, proteinuria.

Potentially Fatal: Hepatotoxicity; angioedema..

4.10 Overdose

Symptoms of acute poisoning include nausea, vomiting, diarrhoea, extreme thirst, coldness, tingling and itching of the skin, tachycardia, vasospastic reactions, respiratory depression, confusion, convulsions and coma. Angina, hypertension or hypotension may also occur. Treatment would have to be symptomatic.

Accidental administration of ergometrine-containing medicinal products to the newborn infant has been reported and has proved fatal. In these accidental neonatal overdosage cases,

symptoms such as respiratory depression, convulsions, cyanosis, oliguria, hypertonia and heart arrhythmia have been reported. Treatment has been symptomatic in most cases; respiratory and cardiovascular support have been required.

5.0 Pharmacological Properties

5.1 Pharmacodynamic Properties

Griseofulvin is a mycotoxic metabolic product of Penicillium spp. It was the first available oral agent for the treatment of dermatophytoses and has now been used for more than forty years. 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. Following oral administration, griseofulvin is deposited in the keratin precursor cells and has a greater affinity for diseased tissue. The drug is tightly bound to the new keratin which becomes highly resistant to fungal invasions. Once the keratin-Griseofulvin complex reaches the skin site of action, it binds to fungal microtubules (tubulin) thus altering fungal mitosis.

5.2 Pharmacokinetic properties

Griseofulvin is a fungistatic antibiotic that inhibits fungal cell division at metaphase and binds to human keratin making it resistant to fungal infections. It has activity against common dermatophytes including epidermophyton, Microsporum, or Trichophyton spp.

Absorption

Variably and incompletely absorbed from the GI tract (oral), may be increased by decreasing particle size and admin with fatty meals; peak plasma concentrations after 4 hours.

Distribution

Keratin precursor cells, stratum corneum of the skin and nails. Protein-binding: 84%.

Metabolism

Hepatic; conveted to 6-demethylgriseofulvin and few glucuronide conjugates.

Excretion

Via urine (<1% as unchanged; 6-demethylgriseofulvin, and glucuronide conjugates), via faeces (large amount of reduced particle size), via sweat; 9-24 hours (elimination half-life).

5.3 Preclinical safety data

There are no pre-clinical data of any relevance to the prescriber, which are additional to those already included in other sections.

6.0 Pharmaceutical Particulars

- ✓ Maize Starch BP
- ✓ Microcrystalline Cellulose BP
- ✓ Dibasic calcium phosphate BP
- ✓ Methyl Hydroxybenzoate BP
- ✓ Propyl Hydroxybenzoate BP

- ✓ Purified Talc BP
- ✓ Magnesium Stearate BP
- ✓ Sodium Starch Glycolate BP
- ✓ Sodium laurel sulphate BP

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

<36 Months>

6.4 Special Precautions for Storage

Store in cool place. (Below 25^0C).Protect from light and humidity.

Keep all medicines out of reach of the children.

6.5 Any Other Information:

Not Applicable

6.6 Nature and Contents of Container

1x20 tablets are packed in ALU-PVC blister in a unit carton along with pack insert.

6.7 Special Precautions for Disposal and Other Handling

None

7.0 Registrant/Sole Agent

EMBASSY PHARMACEUTICAL & CHEMICAL LTD.

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Lagos, Nigeria. Tel.: 01-2900791

8. Manufacturer

LABORATE PHARMACEUTICALS INDIA LIMITED

51, Indl. Area, Gondpur, Paonta Sahib, H.P. (INDIA)

HO: E-11, Industrial Area, Panipat – 132 103.

9. Date of Revision of Text

To be given after approval of product

10. Dosimetry (If applicable)

Not applicable

11. Instructions for Preparation of Radiopharmaceuticals (If applicable)

Not applicable