SUMMARY OF PRODUCTS CHARACTERISTICS

1. NAME OF THE FINISHED PHARMACEUTICAL PRODUCT:

1.1 Brand Name	:	**Griseben-125 Tablet**
1.2 Generic Name	:	Griseofulvin Tablets BP 125mg
1.3 Strength	:	Griseofulvin BP 125mg/Tab.
1.4 Pharmaceutical Form	:	Tablet

2. QUALITATIVE & QUANTITATIVE COMPOSITION:

Each uncoated tablet contains:

Griseofulvin BP 125 mg

3. PHARMACEUTICAL FORM

Tablet

A white colour, round shaped, biconvex, uncoated tablet, having a central breakline on one face of each tablet.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Dermatophyte infections of the skin, scalp, hair and nails where topical therapy has failed or is inappropriate. Tinea capitis caused by Trichophyton tonsurans.

4.2 Posology and method of administration

Dermatophyte infections of the skin, scalp, hair and nails where topical therapy has failed or is inappropriate: Adult: 500 mg daily, increased if necessary to 1 g daily, for severe infections; reduce dose when response occurs, daily dose may be taken once daily or in divided doses.

Tinea capitis caused by Trichophyton tonsurans : Adult: 1 g once daily, alternatively 1 g daily in divided doses.

4.3 Contraindications

Griseben Tablet (Griseofulvin) may contraindicated in acute porphyrias, systemiclupus erythematosus (risk of exacerbation). It also contraindicated in individuals with a history of hypersensitivity to Griseofulvin & low level of granulocytes in the blood, abnormal liver function tests.

4.4 Special warnings and special precautions for use

Hepatic And Renal Impairment : Griseofulvin should be avoided in severe renal and hepatic impairment. Avoid in severe liver disease.

Cautions And Warnings : Periodic monitoring of organ system function, including renal, hepatic and hematopoietic, should be done.

Conception And Contraception : Effective contraception required during and for at least 1 month after administration to women (important: effectiveness of oral contraceptives may be reduced, additional contraceptive precautions e.g. barrier method, required). Men should avoid fathering a child during and for at least 6 months after administration.

4.5 Interaction with other FPPs and Other forms of Interaction

Effects of alcohol possibly enhanced by Griseofulvin, plasma concentration of Ciclosporin possibly reduced by Griseofulvin, anticoagulant effect of Coumarins reduced by Griseofulvin, anecdotal reports of contraceptive failure and menstrual irregularities when Griseofulvin given with Oestrogens & Progestogens. Phenobarbital & Primidone reduces absorption of Griseofulvin.

4.6 Pregnancy and lactation

Animal studies have revealed evidence of fetotoxicity and teratogenicity. Griseofulvin is assigned to pregnancy category C. There are no data on the excretion of Griseofulvin into human milk. It should not be used during pregnancy and lactation.

4.7 Effects on ability to drive and use machines

Griseofulvin may impair performance of skilled tasks (e.g. driving); effects of alcohol enhanced.

4.8 Undesirable effects

Common or very common: Diarrhoea, epigastric discomfort, headache, nausea, vomiting. **Uncommon:** Appetite decreased, confusion, coordination, abnormal, dizziness, drowsiness, insomnia, irritability, peripheral neuropathy, photosensitivity reaction, skin reactions, taste altered, toxic epidermal necrolysis. **Rare or very rare:** Anaemia, hepatic disorders, leucopenia, neutropenia, systemic lupus erythematosus (SLE).

4.9 Overdose & Treatment

Symptoms of a Griseofulvin overdose are not well known but might include nausea, vomiting, diarrhea, headache, numbness and tingling, and confusion. Treatment should be as directed by the physician.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Anti-fungal

Griseofulvin is fungicidal for growing cell and fungistatic for older dormant cells. Griseofulvin binds to tubulin, interfering with microtubule function, thus inhibiting mitosis. It binds to keratin in keratin precursor cells and makes them resistant to fungal infections. The drug reaches its site of action only when hair or skin is replaced by the keratin-Griseofulvin complex. Griseofulvin then enters the dermatophyte through energy-dependent transport processes and bind to fungal microtubules. This alters the processing for mitosis and also underlying information for deposition of fungal cell walls.

5.2 Pharmacokinetic properties

The absorption of Griseofulvin from gastrointestinal tract is variable and incomplete. On average less than 50% of the oral dose is absorbed. The volume of absorption is about 0.7/kg and 80% bound to plasma proteins, Griseofulvin crosses the placenta and may be excreted in breast milk. There is a selective deposition of Griseofulvin in newly formed keratin of hair, skin and nails which gradually moves to the surface of these appendages. It undergoes metabolism to inactive metabolites, principally 6-desmethylgriseofulvin or its glucuronide conjugates. The Metabolites is excreted in the urine with less than 1% of administered dose being excreted as unchanged Griseofulvin. The reminder of dose, principally as metabolites is excreted in bile and faeces.

5.3 Preclinical safety data

None Known

6. PHARMACEUTICAL PARTICULARS

6.1 List of Excipients

SN	Ingredients	Spec.
01.	Microcrystalline Cellulose (M102)	BP
02.	Starch (Maize)	BP
03.	Sod. Methyl Hydroxybenzoate (Sodium Methylparaben)	BP
04.	Sod.Propy Hydroxybenzoate (Sodium Propylparaben)	BP
05.	Purified Talc (Talcum)	BP
06.	Magnesium Stearate	BP
07.	Sodium Starch Glycolate	BP
08.	Sodium Lauryl Sulfate	BP
09.	Purifified Water	BP

6.2 Incompatibilities

Not Known

6.3 Shelf life

36 months

6.4 Special precautions for storage

Protect from light. Keep away from moisture. Keep out of reach of children. Store at a temperature not exceeding 30°C.

6.5 Nature and contents of container

10 blisters of 10 tablets packed in an inner carton. (10’s x 10)

6.6 Instructions for use and handling

Please see the package insert.

7. MARKETING AUTHORISATION HOLDER AND MANUFACTURING SITE ADDRESS

LEBEN LABORATORIES PVT. LTD.,

Business Address:

RO & Works : Plot No. L-4 & L-15, Phase-III, MIDC,
AKOLA–444 104 (MS), INDIA
Ph.:0091-724-2259401/02/03 & Fax: 0091-724-2258371
E-mail- export@lebenlab.com, qad@lebenlab.com, ra@lebenlab.com

Mumbai Off. : 11, Mahavir Mansion, 70, Trinity Street, Near Metro Cinema,
MUMBAI–400 002 (MS), INDIA
Ph.: 0091-22-2207-5301, 02, Fax: 0091-22-2207-5303
E-mail – mumbai@lebenlab.com.

Country : INDIA

8. MARKETING AUTHORISATION NUMBER
07114/08328/REN/2022

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION
Feb 9, 2022

10. DATE OF REVISION OF THE TEXT
01/01/2023