SUMMARY OF PRODUCTS CHARACTERISTICS

1. NAME OF THE FINISHED PHARMACEUTICAL PRODUCT :

1.1	Brand Name	:	**Griseben-500 Tablet**
1.2	Generic Name	:	Griseofulvin Tablets BP 500mg
1.3	Strength	:	500 mg per tablet
1.4	Pharmaceutical Form	:	Tablet

2. QUALITATIVE & QUANTITATIVE COMPOSITION :

Each uncoated tablet contains:

Griseofulvin BP 500 mg.

3. PHARMACEUTICAL FORM

Tablet

White coloured, round shaped, flat beveled uncoated tablet having central breakline on one face of each tablet.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Griseben-500 Tablet is indicated in dermatophyte infections of the skin, scalp, hair and nails where topical therapy has failed or is inappropriate and also in 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: 500mg daily increased if necessary to 1g 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: 1g once daily, alternatively 1g daily in divided doses.

4.3 Contraindications:

Griseben Tablet (Griseofulvin) may contraindicated in acute porphyrias, systemic lupus 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:

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

Hepatic and Renal Impairment: Griseofulvin should be avoided in Hepatic and Renal Impairment. Avoid in severe liver disease.

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.

Conception & 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 eg. barrier method, required). Men should avoid fathering a child during and for at least 6 months after administration.

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 and Treatment

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

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Anti-fungal

Mechanism of action:

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 6desmethylgriseofulvin 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.	Starch (Maize)	BP
02.	Lactose	BP
03.	Sod. Methyl Hydroxybenzoate	BP
04.	Sod. Propyl Hydroxybenzoate	BP
05.	Purified Talc (Talcum)	BP
06.	Magnesium Stearate	BP
07.	Sodium Starch Glycolate	BP
08.	Colloidal Anhydrous Silica	BP
09.	Purified water	BP

6.2 Incompatibilities

Not Known

6.3 Shelf life

36 months

6.4 Special precautions for storage

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

6.5 Nature and contents of container

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

6.6 Instructions for use and handling

Please see the package insert.

7. MARKETING AUTHORISATION HOLDER AND MANUFACTURING SITE ADDRESS

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8. MARKETING AUTHORISATION NUMBER
AMD/12/2002 & AMD/6/2002:

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION
a) Date of first authorization: 21/01/1989.
b) Date of latest renewal: 01/01/2018.

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