SUMMARY OF PRODUCT CHARACTERISTICS
GRISOZEN 125 (Griseofulvin Tablets 125 mg)

1. NAME OF THE MEDICINAL PRODUCT

GRISOZEN 125 (Griseofulvin Tablets 125 mg)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each uncoated tablet contains 125 mg griseofulvin.

Excipients with known effect:

Each tablet contains 10 mg lactose (as lactose monohydrate). For warnings, see section 4.4.

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Tablet (uncoated).

White, circular, uncoated tablet.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

The treatment of fungal infections of the skin, scalp, hair or nails (tinea barbae, tinea capitis, tinea corporis, tinea cruris, tinea pedis, tinea unguium) where topical therapy is considered inappropriate, or the infection has proven refractory to topical therapy.

Prior to therapy, the type of fungi responsible should be identified. The use of griseofulvin is not justified in the treatment of minor or trivial infections that will respond to topical therapy. Consideration should be given to national and/or local guidance on the appropriate use of antifungals.

4.2 Posology and method of administration

General

Oral administration. Tablets should be swallowed whole with a glass of water. Griseofulvin is recommended to be taken after a high-fat meal for increased absorption and to minimise GI distress. General hygiene measures should be observed to control sources of infection or reinfection. Concomitant use of appropriate topical agents is usually required, particularly for tinea pedis.

Adults

The usual dose is 125 mg to 1,000 mg daily; the dose should not be less than 10 mg/kg body weight/day. The dose may be administered as a single daily dose or in two divided doses. Twice-daily dosing may be more effective in patients who respond poorly to once-daily dosing.

Paediatric population

The usual dose is 10 mg/kg body weight/day in divided doses. The tablet formulation is only suitable for children able to swallow tablets.

Hepatic impairment

Griseofulvin is contraindicated in patients with severe hepatic impairment. No dose adjustment is required in mild to moderate hepatic impairment; however, griseofulvin may lead to further impairment of hepatic function, and regular monitoring of liver function is mandated.

Renal impairment

No dose adjustment is required in renally impaired patients; renal insufficiency does not lead to accumulation.

Elderly

No dose adjustment is required in the elderly. Consideration should be given to the possibility of concurrent hepatic impairment.

Duration of therapy

Therapy should be continued for at least two weeks after all signs of infection have disappeared. Indicative durations: tinea corporis 2–4 weeks; tinea capitis 4–8 weeks (up to 8–12 weeks in refractory cases); tinea pedis 4–8 weeks; tinea unguium 6–12 months.

4.3 Contraindications

- Hypersensitivity to griseofulvin or to any of the excipients listed in section 6.1.
- Porphyria.
- Severe hepatic impairment.
- Systemic lupus erythematosus (SLE).
- Pregnancy (see section 4.6).
- Breast-feeding (see section 4.6).

4.4 Special warnings and precautions for use

Hepatic effects

Griseofulvin is contraindicated in severe hepatic impairment. In mild to moderate hepatic impairment, griseofulvin may cause further deterioration of hepatic function. Regular periodic liver function tests are recommended.

Systemic lupus erythematosus

Griseofulvin has been reported to exacerbate SLE. Patients with pre-existing SLE should be excluded from therapy.

Tumorigenic potential

Animal data indicate that long-term administration of high doses of griseofulvin induces tumours in some species. The clinical relevance to humans is unknown, but griseofulvin should not be used prophylactically.

Contraception

Griseofulvin is a liver microsomal enzyme inducer and may impair the effectiveness of oral contraceptives. Women of childbearing age using oral contraception must use additional barrier methods of contraception during therapy and for 4 weeks following therapy cessation.

Griseofulvin causes chromosomal abnormalities in animals. Sexually active males should use an effective barrier method of contraception throughout therapy and for 6 months after therapy termination.

Cross-sensitivity with penicillins

A theoretical possibility of cross-sensitivity exists in patients known to be allergic to penicillins. Caution should be exercised, although such patients have been satisfactorily treated with griseofulvin without adverse sequelae.

Photosensitivity

Patients should avoid excessive exposure to sunlight or UV sources, including sunbeds, during griseofulvin therapy, as photosensitivity reactions can occur.

Alcohol

Consumption of alcohol in association with griseofulvin can result in an "Antabuse"-type reaction. Patients should avoid alcoholic beverages and medicines containing alcohol during griseofulvin therapy.

Long-term therapy

In patients undergoing long-term griseofulvin therapy (e.g. for tinea unguium), periodic monitoring of blood chemistry is recommended, particularly for patients with pre-existing blood disorders, as griseofulvin may cause blood disorders.

Non-susceptible organisms

As with any antibiotic, therapy with griseofulvin may result in overgrowth of non-susceptible organisms (bacteria, yeasts or non-dermatophyte fungi) that are often cofactors in tinea infections, especially tinea pedis. Additional therapy is required to control such organisms.

Griseofulvin is not effective in infections due to Candida albicans, Aspergillus species, Malassezia furfur (pityriasis versicolor) or Nocardia species, and has no antibacterial effects.

Dipstick proteinuria

False positive readings may be obtained in semi-quantitative determination of total urine protein by dipstick tests. Verification by alternative analytical methods (e.g. Biuret method, turbidimetric or dye-binding methods) is recommended.

Lactose content

This product contains 10 mg lactose per tablet. Patients with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption should not take this medicine.

4.5 Interaction with other medicinal products and other forms of interaction

Effect of griseofulvin on other medicinal products

Griseofulvin is a liver microsomal enzyme inducer and may depress plasma levels and efficacy of medicinal products metabolised by cytochrome P450 3A4.

Ciclosporin:

Concomitant administration may result in a reduction of ciclosporin plasma levels, necessitating dose adjustment. Plasma levels of ciclosporin should be monitored during griseofulvin therapy.

Coumarin anticoagulants:

Efficacy may be reduced. Prothrombin time and INR should be regularly monitored during griseofulvin therapy and for 8 days after cessation.

Methadone:

Depression of methadone plasma levels may occur. Patients should be closely monitored for loss of efficacy or plasma levels monitored with corresponding dose adjustments.

Oral contraceptives:

Efficacy is reduced during griseofulvin therapy and for four weeks post-cessation. All sexually active patients should use additional barrier contraception throughout therapy and for 4 weeks (females) and 6 months (males) after cessation (see sections 4.4 and 4.6).

Effect of other medicinal products on griseofulvin

Concurrent administration of enzyme-inducing medicinal products (barbiturates such as phenobarbitone, doxercalciferol, phenylbutazone, primidone, and other sedative and hypnotic drugs that induce metabolising enzymes) may result in a reduction of griseofulvin blood plasma levels and efficacy.

Food (especially high-fat meals) increases absorption of griseofulvin; administration after food is recommended. Alcohol may enhance the CNS effects of griseofulvin and may cause an "Antabuse"-type reaction (see section 4.4).

4.6 Fertility, pregnancy and lactation

Pregnancy

Griseofulvin is contraindicated in pregnancy. There are case reports of human foetal abnormalities associated with griseofulvin. Griseofulvin has been shown to be teratogenic and embryotoxic in mice and rats. Women of childbearing potential must use effective contraception during treatment and for at least 4 weeks after cessation.

Male-mediated effects

Griseofulvin has been shown to induce chromosomal aberrations in animal spermatocytes. Men should use barrier contraception to avoid fathering children for the duration of therapy and for 6 months after cessation.

Breast-feeding

Griseofulvin is contraindicated during breast-feeding. It is unknown whether griseofulvin is excreted in human breast milk, but the possibility exists. The potential risk to the infant cannot be assessed.

Fertility

Griseofulvin can induce aneuploidy and meiotic delay in mouse oocytes and causes increases in numerical and structural chromosome aberrations in mouse spermatocytes. The implications for human fertility are unknown.

4.7 Effects on ability to drive and use machines

Griseofulvin has no or negligible influence on the ability to drive and use machines. However, it may cause drowsiness, confusion, dizziness and impaired co-ordination. Patients should be cautioned not to drive or operate machines until they are sure they are not affected.

4.8 Undesirable effects

Headache and gastric discomfort are the most common effects on starting treatment, but usually disappear as treatment continues.

System Organ Class	Frequency	Adverse Reaction
Blood and lymphatic disorders	Rare	Leucopenia, neutropenia, anaemia — usually resolve on cessation

System Organ Class	Frequency	Adverse Reaction
Nervous system disorders	Common / Uncommon	Headache (common); impaired co-ordination, peripheral neuropathy, confusion, dizziness, drowsiness, insomnia, irritability (uncommon)
Gastrointestinal disorders	Common / Uncommon	Diarrhoea, vomiting, nausea, gastric discomfort (common); anorexia, taste sensation changes (uncommon)
Skin and subcutaneous tissue disorders	Uncommon / Rare	Toxic epidermal necrolysis, erythema multiforme, photosensitivity (uncommon); precipitation of SLE, bullous reactions including Lyell's syndrome, urticaria, skin rashes (rare)
Hepatobiliary disorders	Very rare	Alteration in liver function tests (elevation >3× ULN), intrahepatic cholestasis, hepatitis

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the National Regulatory Authority.

4.9 Overdose

Symptoms

No case of overdose has been reported. Likely symptoms would include nausea, vomiting, headache, numbness and tingling, confusion, and vertigo. Urticaria or porphyria could occur.

Treatment

There is no specific antidote. Gastric lavage or induction of emesis may be helpful if ingestion is recent. Activated charcoal may also be of use. Treatment should be symptomatic and supportive. Laboratory monitoring of haematopoietic, hepatic and nephritic parameters and electrolytes is recommended.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Antifungals for systemic use. ATC code: D01BA01.

Griseofulvin is an antifungal antibiotic active in vivo against common dermatophytes. It binds to tubulin at distinct binding sites, interfering with microtubule function and causing inhibition of mitosis (arresting cell division), leading to the production of multinucleate cells of characteristic morphology. Griseofulvin binds to keratin in keratin precursor cells, making newly formed keratin resistant to fungal infection.

Griseofulvin has antifungal activity against: Trichophyton rubrum, T. tonsurans, T. mentagrophytes, T. interdigitalis, T. verrucosum, T. megnini, T. gallinae, T. crateriform, T. sulphureum and T. schoenleinii; Microsporum audouinii, M. canis, M. gypseum; Epidermophyton floccosum. It has no activity against non-dermatophyte fungi, yeasts, or bacteria.

5.2 Pharmacokinetic properties

Absorption

Absorption from the gastrointestinal tract is variable and incomplete (on average less than 50% of the oral dose absorbed). Administration after a fatty meal and reduction in particle size increase the rate and extent of absorption. Peak plasma levels (0.5–1.5 µg/ml after a 125 mg dose; 1.5–3.0 µg/ml after a 1,000 mg dose) are reached in 2–4 hours and maintained for approximately 10–20 hours. Griseofulvin exhibits linear pharmacokinetics.

Distribution

Volume of distribution approximately 0.7 L/kg; approximately 80% bound to plasma proteins, predominantly albumin. Griseofulvin crosses the placenta. There is selective deposition in newly formed keratin of hair, skin and nails.

Biotransformation

Griseofulvin undergoes metabolism to inactive metabolites, principally 6-desmethylgriseofulvin or its glucuronide conjugate.

Elimination

Terminal plasma half-life ranges from 9.5–21 hours with considerable intersubject variability. The majority of the dose is excreted in urine as metabolites; less than 1% is excreted as unchanged griseofulvin. The remainder is excreted in bile and faeces. Renal insufficiency does not lead to accumulation.

5.3 Preclinical safety data

Griseofulvin can induce aneuploidy and meiotic delay in mouse oocytes at high doses (≥250 mg/kg), and causes numerical and structural chromosome aberrations in mouse spermatocytes (≥125 mg/kg). Griseofulvin administered to rats and mice during pregnancy has been associated with foetotoxicity and foetal malformations. Long-term administration of high doses has been reported to induce hepatomas in mice and thyroid tumours in rats (not hamsters); the effects in mice may be due to a species-specific effect on porphyrin metabolism.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

No.	Excipient
1	Lactose monohydrate (excipient with known effect — 10 mg per tablet)
2	Maize starch
3	Microcrystalline cellulose
4	Hydroxypropylmethylcellulose (HPMC)
5	Purified water
6	Purified talc
7	Magnesium stearate
8	Colloidal anhydrous silica
9	Croscarmellose sodium

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

36 months.

6.4 Special precautions for storage

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

6.5 Nature and contents of container

ALU-PVC blister of 10 tablets; 10 such blisters packed in one primary carton with package insert. Pack size: 100 tablets.

6.6 Special precautions for disposal and other handling

No special requirements. Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

ZAIN PHARMA LTD.

Plot No. 209/13741, Colchester Park,

Go-Down No. 1, 2, 3, Off Mombasa Road,

Behind Nice and Lovely House,

P.O. Box: 100167-00101, Nairobi, Kenya.

8. MARKETING AUTHORISATION NUMBER (PPB REGISTRATION NUMBER)

H2025/CTD12790/27008

9. DATE OF FIRST AUTHORISATION / RENEWAL OF AUTHORISATION

05.11.2025

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