Legal Category
POM: Prescription only medicine

- **SmPC**

1. Name of the medicinal product
GRISOKRIS SUSPENSION

2. Qualitative and quantitative composition
Each 5 ml contains:
Griseofulvin USP 125 mg
For the full list of excipients, see section 6.1.

3. Pharmaceutical form
Suspension

4. Clinical particulars

4.1 Therapeutic indications
GRISOKRIS SUSPENSION is an antifungal medicine. It is used to treat certain kinds of fungal or yeast infections of the skin, hair, or nails.

4.2 Posology and method of administration

Posology

Adults

Normally 500 to 1000 mg daily, but not less than 10 mg/kg bodyweight daily. A single dose daily is often satisfactory, but divided doses may be more effective in patients who respond poorly.

Paediatric population

Usually 10 mg/kg (5 mg/lb) body weight daily in divided doses.

Duration of Treatment

This depends upon the thickness of keratin at the site of infection. For hair or skin at least four weeks treatment is required, whereas toe or fingernails may need six to twelve months treatment. Therapy should be continued for at least two weeks after all signs of infection have disappeared.

Method of administration

For oral administration.

Doses should be taken after meals, otherwise absorption is likely to be inadequate.

4.3 Contraindications
Porphyria or severe liver disease. Griseofulvin may cause liver disease to deteriorate, and liver function should be monitored in such conditions.

Systemic Lupus Erythematosus: griseofulvin has been reported to exacerbate the condition

There is no evidence of the safety of Griseofulvin in human pregnancy. Griseofulvin is teratogenic in animals and some case reports of human foetal abnormalities have been observed. Therefore, Griseofulvin should not be used in pregnancy, or in women intending to become pregnant within one month following cessation of treatment.

4.4 Special warnings and precautions for use
None

4.5 Fertility, pregnancy and lactation

Pregnancy

There is no evidence of its safety in human pregnancy (see contraindications). Griseofulvin has been shown to be teratogenic in mice and rats following administration to pregnant animals. Some case-reports suggest that it produces human foetal abnormalities.

As Griseofulvin is capable of inducing aneuploidy (abnormal segregation of chromosomes following cell division) in mammalian cells exposed to the compound in vitro and in vivo, women

should be warned that they should not take the drug during pregnancy or become pregnant within one month following cessation of treatment
Additionally, males should not father children within six months of treatment.
Breast-feeding
It is not known if griseofulvin is excreted in human milk. Safety in children of mothers who are breast-feeding has not been established.

4.6 Effects on ability to drive and use machines

In those rare cases where individuals are affected by drowsiness while taking griseofulvin, they should not drive vehicles or operate machinery.

4.7 Undesirable effects

Diarrhoea, nausea and vomiting are common adverse events.

Headache and gastric discomfort sometimes occur, but usually disappear as treatment continues. On rare occasions urticarial reactions, skin rashes and precipitation of Systemic Lupus Erythematosus have been reported.

Toxic epidermal necrolysis and erythema multiforme have been reported.

Significant elevations in LFTs (greater than three times the upper limit of normal) have been reported very rarely.

There have been reports of central nervous system effects e.g. confusion, dizziness, impaired co-ordination and peripheral neuropathy.

Leucopenia with neutropenia has been reported.

Photosensitivity reactions can occur on exposure to intense natural or artificial sunlight.

Drowsiness has been reported.

Reporting of suspected adverse reactions

4.8 Overdose

Treatment is unlikely to be required in cases of acute overdosage.

5. Pharmacological properties

5.1 Pharmacodynamic properties

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

Mechanism of action

Griseofulvin is an antifungal antibiotic which is active in vitro against common dermatophytes. It exerts its antifungal effect by disrupting the cell division spindle apparatus of fungal cells, thereby arresting cell division.

A prominent morphological manifestation of the action of griseofulvin is the production of multinucleate cells as the drug inhibits fungal mitosis.

Griseofulvin causes disruption of the mitotic spindle by interacting with polymerised microtubules while the effects of the drug are thus similar to those of colchicine and vinca alkaloids, its binding sites on the microtubular protein are distinct.

5.2 Pharmacokinetic properties

Absorption

The absorption of griseofulvin from the gastrointestinal tract is variable and incomplete. On average, less than 50% of the oral dose is absorbed, but fatty foods and a reduction in particle size will increase the rate and extent of the absorption.

Distribution

After oral dosing there is a phase of rapid absorption followed by slower prolonged absorption. Peak plasma levels (0.5 - 1.5 micrograms after a 500mg oral dose) are achieved by 4 hours and are maintained for 10 - 20 hours. The terminal plasma half-life ranges from 9.5 - 21 hours, there being considerable intersubject variability. In plasma griseofulvin is approximately 84% bound to plasma proteins, predominantly albumin.

Elimination

The absorbed griseofulvin is excreted in the urine mainly as 6-desmethylgriseofulvin or its glucuronide conjugate.

There is selective deposition of griseofulvin in newly formed keratin of hair, nails and skin, which gradually moves to the surface of these appendages.

5.3 Preclinical safety data

None.

6. Pharmaceutical particulars

6.1 List of excipients

SODIUM ALGINATE
SODIUM BENZOATE
SODIUM SACCHARIN
SUCROSE
MENTHOL
PURIFIED WATER

6.2 Incompatibilities

There are no significant incompatibilities with the product.

6.3 Shelf life

3 years.

6.4 Special precautions for storage

Store in a cool dry place in the original package.

6.5 Nature and contents of container

60 ml amber PET Bottle provided with a measuring cup.

6.6 Special precautions for disposal and other handling

No special requirements for disposal.

7. Marketing authorisation holder

Krishat Pharma Industries Limited KM 15, Lagos-Ibadan Expressway, Ibadan, Oyo State, NIGERIA.
Email: info@krishatpharma.com

8. Marketing authorisation number(s)

NA

9. Date of first authorisation/renewal of the authorisation

NA

10. Date of revision of the text

NA

Company contact details
Address
Krishat Pharma Industries Limited KM 15, Lagos-Ibadan Expressway,Ibadan, Oyo State,

NIGERIA.
Medical Information e-mail
Email: info@krishatpharma.com