1. Name of the medicinal product

GRISULF CREAM

2. Qualitative and quantitative composition

Griseofulvin 1% w/w.

For excipients, see 6.1

3. Pharmaceutical form

Cream

4. Clinical particulars

4.1 Therapeutic indications

The treatment of tinea pedis (athlete's foot).

4.2 Posology and method of administration

Method of Administration:

Cutaneous use; to be applied topically to the feet.

When applied to the feet it may be necessary to hold the toes apart to reveal the full area to be treated. The affected areas should be washed, dried thoroughly and flaking skin removed before applying with Grisulf.

Posology:

Adults: The cream should be applied thinly and evenly to the affected area 2 – 3 times daily and rubbed in gently. A strip of cream (½ cm long) is enough to treat an area of about the size of the hand.

If the feet are infected, they should be thoroughly washed and dried, especially between the toes, before applying the cream.

Clinical improvement usually occurs between two and four weeks. It is important to use the Grisulf regularly as premature stoppage of treatment can cause the infection to re-occur. To prevent relapse, treatment should be continued for ten days after all the lesions have disappeared. Treatment period should not exceed four weeks. If there is no improvement within four weeks, a physician should be consulted

Elderly: For the treatment of infection in the elderly the dosage instructions are the same as those given for adults. There are no additional specific instructions.

Children: Not to be used in children under 16 years of age

* If more than one dose is necessary the first dose should be allowed to dry for a few seconds before the second application which similarly should be allowed to dry prior to a third application.

4.3 Contraindications

Hypersensitivity to griseofulvin or organic solvents.

4.4 Special warnings and precautions for use

Grisulf is for external use only and should only be applied to the feet. Do not apply onto any other parts of the body. Avoid applying Grisulf into the eyes. The solution should not be allowed to come into contact with mucous membranes.

Caution should be exercised when using Grisulf on broken skin as the solution may cause stinging.

The adverse reactions associated with oral griseofulvin therapy have not been reported in association with topical administration.

4.5 Interaction with other medicinal products and other forms of interaction

None known

4.6 Pregnancy and lactation

Systemic treatment with griseofulvin should be avoided in pregnancy and although human studies have not shown any significant absorption into the systemic circulation following topical administration of Grisulf, safety in human pregnancy or lactation has not been established, and therefore it should not be used unless the practitioner considers that the benefit of treatment outweighs the risk.

4.7 Effects on ability to drive and use machines

None known

4.8 Undesirable effects

Grisulf may cause skin irritation, i.e. slight stinging or burning on application, although this is unlikely to necessitate discontinuation of treatment.

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.

4.9 Overdose

If Grisulf is accidentally ingested, overdosage from griseofulvin active ingredient is unlikely to require treatment, however the component solvents could give rise to symptoms of alcoholic intoxication and poisoning so that gastric lavage and emesis may be required. Any additional treatment should be symptomatic and supportive.

Grisulf contains an alcohol base which will cause burning and irritation to the eyes. In the event that Grisulf is accidentally sprayed into the eyes, the area should be bathed with large amounts of cool tap water.

5. Pharmacological properties

5.1 Pharmacodynamic properties

The active ingredient of Grisulf, griseofulvin, is an antifungal agent which, when applied topically in this formulation, penetrates the skin in the tissues of which it remains active against dermatophyte infections even after subsequent evaporation of the solvent system.

Grisulf is active against dermatophytes including microsporum canis, trichophyton rubrum and trichophyton verrucosum.

5.2 Pharmacokinetic properties

Studies in humans have demonstrated no significant absorption.

When taken orally griseofulvin is metabolised by the liver mainly to 6-desmethyl-griseofulvin which is excreted in the urine. A large amount of an oral dose of griseofulvin is excreted unchanged in faeces and a small amount in urine; some is excreted in sweat.

5.3 Preclinical safety data

Animal studies undertaken with respect to Grisulf relate appropriately to local toxicity and absorption.

Twenty-eight day studies of the effects of griseofulvin, benzyl alcohol, acetone and isopropyl alcohol on the skin of rabbits showed few signs of dermal irritation.

Systemic absorption after topical administration of Grisulf to shaved rats is poor, being approximately 20% in 24 hours. The data suggest a reduced systemic absorption in man by the topical route and a much more favourable distribution between the dermis and the skin.

In human volunteer studies, serum concentrations after topical administration of high doses are too small to be measured.

6. Pharmaceutical particulars

6.1 List of excipients

S/NO	INGREDIENTS	QUANTITY/ (KG)
1.	**Water**	
2.	Liquid paraffin	
3	Emulsifying wax	
4	Cetostearyl alcohol	
5	Stearic acid	
6	Propylene glycol	
7.	Benzyl alcohol	

6.2 Incompatibilities

None Known

6.3 Shelf life

3 years

6.4 Special precautions for storage

Do not store above 25°C. Protect from direct light and heat. Highly flammable, keep away from naked flames.

6.5 Nature and contents of container

15g

6.6 Special precautions for disposal and other handling

No special requirements.

7.0 APPLICANT/MANUFACTURER

7.1 Name and Address

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