

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

GRISOL 1 % Spray Solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Griseofulvin 1% w/w.

Each spray delivers 400 micrograms of griseofulvin (0.05ml per dose).

For excipients, see 6.1.

3 PHARMACEUTICAL FORM

Cutaneous spray, solution.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

The treatment of tinea pedis (athletes 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 spraying with Grisol.

Posology:

Adults: The area covered by one 0.05 ml dose (as delivered by one depression of the spray button), when sprayed from a distance of 2 inches, is approximately 2 square inches.

A dose of one 0.05 ml spray, which may be increased to three* 0.05 ml sprays, if necessary, should be sprayed once daily to each affected area, preferably at the same time of day.

A dosage of 0.05 ml (one spray) daily is recommended for mild athlete's foot. If it is more severe or extensive affecting sides or soles of feet the dose should be increased to 0.15 ml (3 sprays) daily in such resistant cases.

Clinical improvement usually occurs between two and four weeks. It is important to use the Grisol Spray 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

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

Caution should be exercised when using Grisol 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 Fertility, 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 Grisol, 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

Grisol 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. Healthcare professionals are asked to report any suspected adverse reactions via the national reporting system in the United Kingdom: Yellow Card Scheme

Website: www.mhra.gov.uk/yellowcard

4.9 Overdose

If Grisol 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.

Grisol contains an alcohol base which will cause burning and irritation to the eyes. In the event that Grisol 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 Grisol, 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.

Grisol 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 Grisol 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 Grisol 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

Acetone
Benzyl Alcohol
Isopropyl 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

Glass bottles of nominal volume 20 ml, each fitted with a spray pump assembly designed to deliver approximately 0.05 ml per actuation and fitted with a protective plastic cap.

Each bottle is packed in an outer cardboard carton, also containing a patient information leaflet.

6.6 Special precautions for disposal

Highly flammable, keep away from naked flames. Store the container in an upright position.

Before using the spray, one dose should be directed at a piece of waste paper or tissue to make sure the spray nozzle is working properly.

The bottle should be held about two inches away from the skin, pointing the nozzle in the correct direction.

Grisol should not be sprayed into eyes, nose, mouth or other sensitive areas. Grisol should be used on feet only.

7 MARKETING AUTHORISATION HOLDER

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8 MARKETING AUTHORISATION NUMBER(S)

PL 20416/0874

**9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE
AUTHORISATION**

07/04/2009

10 DATE OF REVISION OF THE TEXT

04/06/2024