

# Griseofulvin Powder

**(microsize)**

**FOR ORAL USE IN HORSES**

ANADA 200-391, Approved by FDA



MADE IN USA

## CAUTION

Federal law restricts this drug to use by or on the order of a licensed veterinarian.

## INDICATIONS

Equine ringworm infection caused by *Trichophyton equinum* or *Microsporum gypseum*.

## DESCRIPTION

Griseofulvin Powder (microsize) is available in 15-gram packets each containing 2.5 grams griseofulvin (microsize). Griseofulvin Powder (microsize) is an orally effective antifungal antibiotic specifically active against superficial fungi which cause tinea (ringworm) of the skin and hair. This microsize form of griseofulvin differs from regular Griseofulvin Powder products in that its finer particle size results in a much greater surface area for absorption. An increased blood level has been obtained in experimental studies in man using fine particle size griseofulvin, indicating better absorption and a greater amount of the drug available for fungistatic action in the skin and hair.



## BENEFITS

- **Orally Effective Antifungal Treatment:** Specifically active against superficial fungi which cause tinea (ringworm) of the skin and hair.
- **Microsized:** Finer particle size provides greater surface area for absorption and drug available for fungistatic action in the skin and hair.
- **Economical:** Available in 15-gram packet sizes (2.5 grams Griseofulvin).
- **Ease of Use:** Powder may be given on a small amount of feed or in a drench.
- **Usual Dose:** One half to one packet daily.
- **Safe:** Approved by FDA.

## PACKAGING

LIST NO.	UNIT PACKAGE	CASE SIZE	PALLET
1GRI001	15 g pouch	96 (8 x 12)	5,760

## WARNING

**Do not use in horses intended for human consumption.**

See reverse side for Technical Information.

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## TECHNICAL INFORMATION

# Griseofulvin Powder

(microsize)

FOR ORAL USE IN HORSES



ANADA 200-391, Approved by FDA

### NOT FOR USE IN HUMANS • KEEP OUT OF REACH OF CHILDREN

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#### GENERAL CONSIDERATIONS:

In human medicine, Griseofulvin Powder (microsize) is indicated in the treatment of infections caused by dermatophytic fungi of the skin, hair, and nails. Of those organisms which cause these conditions, the following are responsive to oral therapy with Griseofulvin Powder (microsize): *Trichophyton mentagrophytes*, *Trichophyton rubrum*, *Trichophyton schoenleinii*, *Trichophyton sulphureum*, *Trichophyton verrucosum*, *Trichophyton interdigitale*, *Epidermophyton floccosum*, *Microsporum gypseum*, *Microsporum canis*, *Microsporum audouini*. Griseofulvin Powder (microsize) is inactive against bacteria and yeasts including *Monilia*, *Actinomyces*, *Nocardia*, *Blastomyces*, *Coccidioides*, *Histoplasma*, *Cryptococcus*, *Sporotrichum*, and *Aspergillus*.

The Griseofulvin Powder (microsize) product is administered orally until the fungi have been eliminated from the skin and hair. The length of therapy will vary with the severity of the infection. The time necessary for the newly formed, fungal-resistant keratin to reach the surface varies greatly with different structures, such as hair and thin body skin. Experimental and clinical work indicates that animals showing involvement of skin and hair only may require treatment for 3 to 4 weeks. Cure is considered complete when repeated cultures are negative for the presence of fungi. In the absence of these tests, therapy should be continued until lesions are clinically improved and there is evidence of resumed hair growth.

The infected skin in many cases shows a remarkably rapid improvement, with decreased itching and inflammation occurring in a few days. In some cases the skin may appear normal clinically in as short a time as 10 days. Viable fungi in the outer layers may persist, however, and the possibility of reinfection is not known with certainty. The optimal period of treatment has not yet been determined. Clipping of the hair to help remove any remaining viable fungi is

indicated. Hair that is clipped from the infected lesion should be burned.

#### INDICATIONS:

**Equine** - Ringworm infection caused by *Trichophyton equinum* and *Microsporum gypseum*.

**Adults** - 1 packet per day (2.5 grams).

**Yearlings** - 1/2 to 1 packet per day (1.25-2.5 grams).

**Foals** - 1/2 packet per day.

Cases of ringworm in horses caused by *T. equinum* and *M. gypseum* should be treated with the Griseofulvin Powder (microsize) product for a period of not less than 10 days. Responsive cases may show clinical signs of recovery in 5 to 7 days after griseofulvin therapy is initiated. In responsive cases, treatment should be continued until all infected areas are negative by appropriate culture.

If cases do not respond to therapy in 3 weeks, it is recommended that the diagnosis be reevaluated.

The powder may be given on a small amount of feed or in a drench.

#### WARNING:

Do not use in horses intended for human consumption.

The safety and efficacy of prophylactic use of griseofulvin has not been established. This drug should not be used to treat minor or trivial infections.

Safety of griseofulvin for use in pregnant animals has not been established. It has been reported in the Soviet literature (N.N. Slonitskaya; Teratogenic Effect of Griseofulvin-Forte on the Rat Fetus/Antibiotiki 14(1): 44-48, 1969) that a griseofulvin preparation was found to be embryotoxic and teratogenic on oral administration to pregnant Wistar rats. In addition, pups and kittens with either cleft palates or other abnormalities have been reported in litters of bitches and queens treated with griseofulvin during gestation.

#### PRECAUTIONS:

Patients on prolonged therapy with any potent medication should be under close observation.

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

This antibiotic is derived from a species of *Penicillium griseofulvum*. A number of known penicillin-sensitive humans have been treated with griseofulvin without difficulty. In veterinary medicine, the drug apparently has no allergenic properties; however, considerably more experience in this area must be obtained before definite conclusions may be drawn.

Griseofulvin administered to animals intraperitoneally or intravenously in massive doses will produce damage to the seminal epithelium; however, no such effects have been

observed following oral administration of usual clinical doses to dogs and cats.

Studies to date indicate that the usual clinical doses of griseofulvin administered orally have no effect on spermatogenesis. More evidence is needed, but it appears likely that such effects noted are related to the massive doses administered by the parenteral routes. The effects of griseofulvin on stallion spermatogenesis are not known.

#### SIDE EFFECTS:

Close observation of human and animal patients receiving therapeutic doses thus far reveals no effect on body weight, fasting blood sugar, blood electrolytes, total or differential counts, thymol turbidity tests, urinalyses, or sternal marrow counts.

In the human, heartburn, nausea, epigastric discomfort, and diarrhea have occasionally been reported. In a few instances, urticaria or drug rashes have developed and in these instances the drug should be withdrawn. Generally, the incidence of side effects has been quite low and the drug seems to be well tolerated when given orally.

The veterinarian is alerted to the following griseofulvin-associated side effects which have been reported in either human or veterinary literature: irritability, dizziness, memory loss, visual disturbances, antagonism to barbiturates and other drugs metabolized by the liver, such as warfarin-type anticoagulants.

It has also been reported that griseofulvin effects disturbances in porphyrin metabolism, formation of hepatomata and cocarcinogenicity with methylcholanthrene; also higher fat diet increases absorption of the antibiotic.

#### GENERAL MEASURES:

Clearing of dermatophytic infections with oral griseofulvin therapy is a great advance. However, it is necessary to maintain general hygienic precautions. The possibility of recurrence is not known. Destruction of old bedding, disinfection of stall, a close clipping of hair just before termination of therapy, etc., are measures which should reduce incidence of reinfection.

#### HOW SUPPLIED:

Griseofulvin Powder (microsize) 15-gram packets (2.5 grams of griseofulvin, microsize), cartons of 12.

#### STORAGE:

Store between 2°C and 30°C (36°F and 86°F).

To obtain an MSDS or for assistance, contact Bimeda, Inc. at 1-888-524-6332.

