

**PARTICULARS TO APPEAR ON <THE OUTER PACKAGE> <AND> <THE IMMEDIATE PACKAGE> {NATURE/TYPE}**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Grisol V Powder, 7.5% w/w Oral Powder

**2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES**

Contains 7.5 w/w Griseofulvin

**3. PHARMACEUTICAL FORM**

Oral Powder

**4. PACKAGE SIZE**

Pot of 500g

**5. TARGET SPECIES**

Horses

**6. INDICATION(S)**

For the treatment of ringworm in horses caused by *Trichophyton* species and *Microsporum* species

**7. METHOD AND ROUTE(S) OF ADMINISTRATION**

1 level 5ml measure gives approximately 5g. For oral administration in the feed. 10mg griseofulvin per kg bodyweight daily for 7 consecutive days. This is achieved by administering 10 g per 75 kg bodyweight daily. In severe cases, treatment may be continued for an additional 7 days at the dose rate outlined above. The addition of the product to concentrates fed on an ad-lib basis is not recommended. For further information, see package leaflet.

**8. WITHDRAWAL PERIOD**

Not to be used in animals intended for human consumption. Treated horses may never be slaughtered for human consumption. The horse must have been declared as not intended for human consumption under national horses passport legislation.

**9. SPECIAL WARNING(S), IF NECESSARY**

This product must not be used for the treatment of pregnant or lactating mares. Do not use in horses intended for human consumption. Do not give to animals with impaired liver function. Do not use in animals with known hypersensitivity to the active substance. Prophylactic therapy is advised for in-contact animals only, the normal 7 days course is recommended.

User Warnings:

The product or feed containing the product must not be handled by women of childbearing age. Avoid direct contact with the skin and eyes. Wear impervious glove and mask when administering product. See package leaflet for full user warnings.

Pharmaceutical Precautions:

Griseofulvin is not active against *C.albicans*, *A. funigatus* or other systemic fungal infections. The efficacy of this product can be impaired if used concurrently with substances such as phenylbutazone and sedatives which induce drug metabolizing enzymes.

**10. EXPIRY DATE**

**11. SPECIAL STORAGE CONDITIONS**

Do not store above 25°C. Protect from light. Store away from food, drink and animal feedingstuffs.

**12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY**

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

**13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE [Distribution category]**

POM-V

For Animal Treatment Only

**14. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”**

Keep out of reach and sight of children

**15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER**

Vetoquinol UK Limited  
Buckingham Industrial Park  
Buckingham  
MK18 1PA

**16. MARKETING AUTHORISATION NUMBER(S)**

Vm 08007/4032

**17. MANUFACTURER'S BATCH NUMBER**

Product not marketed

**PACKAGE LEAFLET FOR:**

**1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT**

Vetoquinol UK Limited  
Vetoquinol House  
Great Slade  
Buckingham Industrial Park  
Buckingham  
MK18 1PA

**2. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Grisol V Powder, 7.5% w/w Oral Powder

**3. STATEMENT OF THE ACTIVE SUBSTANCE (S) AND OTHER INGREDIENTS**

**4. INDICATION(S)**

Griseofulvin is an antifungal for the treatment of ringworm in horses. It is active against the dermatophytes causing ringworm, including *Trichophyton verrucosum*, *T. mentagrophytes* *T. rubrum*, *T. equinum*, *Microsporum gypseum* and *M. canis*. Griseofulvin is not active against *Candida albicans*, *Aspergillus fumigatus* and other systemic fungal infections.

**5. CONTRAINDICATIONS**

Grisol V Powder must not be given to animals with impaired liver function. Do not use in animals with known hypersensitivity to the active substance. Do not use in pregnant animals.

**6. ADVERSE REACTIONS**

Long-term administration of griseofulvin with feed has been reported to be hepatotoxic in cats and to induce hepatomas in mice and thyroid tumours in rats but not in hamsters. The clinical significance of these findings for man and the target species is not known.

**7. TARGET SPECIES**

Horses

**8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION**

Administer orally, normally by addition to the feed. Care should be taken with mixing. The recommended dose for griseofulvin is 10mg/kg bodyweight daily for 7 consecutive days. This is achieved by administering 10g per 75kg bodyweight of the product daily.

#### Dosage guide

Bodyweight	Daily dosage
150kg	20g
225kg	30g
300kg	40g
375kg	50g
450kg	60g
525kg	70g
Over 525kg	70g + 10g for each additional 75kg bodyweight

In severe cases, treatment may be continued for an additional 7 days at the dose rate outlined above.

1 level 5ml measure is approximately equal to 5g.

The addition of the product to concentrates fed on an ad-lib basis is not recommended.

Should be administered with the cereal ration and fed individually to affected animals.

### **9. ADVICE ON CORRECT ADMINISTRATION**

### **10. WITHDRAWAL PERIOD(S)**

Not to be used in animals intended for human consumption. Treated horses may never be slaughtered for human consumption. The horse must have been declared as not intended for human consumption under national horses passport legislation.

### **11. SPECIAL STORAGE PRECAUTIONS**

Do not store above 25°C.

Protect from light.

Store away from food, drink and animal feedingstuffs

Keep out of reach and sight of children

### **12. SPECIAL WARNING(S)**

For Animal Treatment Only

**Special precautions for use in animals:**

Customary hygienic measures should be adopted to minimise the risk of re-infection.

Buildings which have housed infected stock should be thoroughly cleaned and disinfected before restocking. All equipment used during the treatment should also be cleaned and disinfected.

**Special precautions to be taken by the person administering the veterinary medicinal product to animals**

Avoid direct contact with the skin and eyes

Impervious gloves must be worn when handling this product or feed containing this product. Handle only in a well-ventilated area and avoid inhaling dust from the product.

Wear either a half-mask respirator conforming to European Standard EN149 or a non-disposable respirator to European Standard EN140 with a filter to EN143 when blending the product with feed. Operator contact should be avoided.

**The product or feed containing the product must not be handled by women of childbearing potential.**

Long-term administration of griseofulvin with feed has been reported to be hepatotoxic in cats and to induce hepatomas in mice and thyroid tumours in rats but not in hamsters. The clinical significance of these findings for man and the target species is not known.

**13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY**

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

**14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED**

Date of revision: September 2008

**15. OTHER INFORMATION**

POM-V

Prescription only medicine – Veterinarian.

*Vm 08007/4032*

## Pharmacological Properties

Griseofulvin is irregularly absorbed from the gastro-intestinal tract. The oral administration of a 0.5g dose of griseofulvin produces peak plasma concentrations of approximately 1g/ml in about 4 hours. Griseofulvin is deposited in keratin precursor cells and is concentrated in the stratum corneum of the skin and in the nails and hair, thus preventing fungal invasion of newly formed cells. Griseofulvin is metabolised in the liver mainly to 6-demethylgriseofulvin which is excreted in the urine. A large amount of griseofulvin appears unchanged in the faeces; less than 1% is excreted unchanged in the urine; some is excreted in sweat.

## Shelf life

Shelf life of veterinary medicinal product as packaged for sale; 2 years

Approved: 17/04/2018



Product not marketed