

**Part II**  
**SUMMARY OF PRODUCT CHARACTERISTICS**

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

Grisol V Granules 7.5%

**2. QUALITATIVE AND QUANTITATIVE COMPOSITION**

Each gram contains 75 mg Griseofulvin

**For a full list of excipients, see section 6.1**

**3. PHARMACEUTICAL FORM**

Granules

**4. CLINICAL PARTICULARS**

**4.1 Target species**

Horses.

**4.2 Indications for use, specifying the target species**

For the treatment of ringworm in horses caused by *Trichophyton spp.* And *Microsporum spp.*

Other systemic fungal infections including those caused by *Candida albicans* and *Aspergillus spp.* do not respond to griseofulvin therapy.

**4.3 Contra-indications**

Not to be used for the treatment of pregnant mares.

**4.4 Special warnings for each target species**

Do not use in horses with severe hepatic impairment.

**4.5 Special precautions for use**

**(i) Special precautions for use in animals**

Buildings occupied by infected animals should be thoroughly cleaned and disinfected; all equipment used during the treatment should also be cleaned and disinfected. These measures will minimise risk of infection. Mix thoroughly with the total feed ration so that the required dose is contained in the amount each animal will consume at one feed. Add to feed immediately prior to administration. Discard any remaining medicated feed.

May be used for the treatment of groups of animals or for individuals. For dosing, animals should be approximately equal in bodyweight. Adequate trough space should be available and shy feeders should be fed individually to ensure adequate dosage.

Prophylactic therapy is advised for in-contact animals only. The normal 7-day course is recommended.

Keep horses away from infected cattle.

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

When handling the product or feed containing the product, wear impervious gloves and either a disposable half-mask respirator conforming to European Standard EN 149 or a non-disposable respirator conforming to European Standard EN 140 with a filter to EN 143.

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

Long-term administration of high doses of griseofulvin with foods has been reported to induce hepatomas in mice and thyroid tumours in rats, but not hamsters. The clinical significance of those findings for man is not known.

**4.6 Adverse reactions (frequency and seriousness)**

Long-term administration of high doses 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 the target species or man is not known. Griseofulvin may be teratogenic (see also 4.5 above)

**4.7 Use during pregnancy, lactation or lay**

Not to be used for the treatment of pregnant mares. It can be safely administered to lactating animals.

**4.8 Interaction with other medicinal products and other forms of interaction**

None.

**4.9 Amounts to be administered and administration route**

Administer orally, by addition to the feed ration. The pack is supplied with a 5ml scoop. 3 level scoops contain approximately 10g of the product.

The recommended dose rate is 10mg griseofulvin per kg bodyweight daily for 7 consecutive days. This is achieved by administering 10g of product per 75kg bodyweight daily. Discard any remaining medicated feed.

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

**4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary**

Not applicable

**4.11 Withdrawal period(s)**

Not to be used in horses 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 horse passport legislation.

## **5. PHARMACOLOGICAL PROPERTIES**

ATC vet code: QD014408

Griseofulvin is an antifungal antibiotic which is absorbed over a prolonged period from the gastrointestinal tract and is deposited in the keratin precursor cells. It concentrates in the stratum corneum of the skin, in the nail and in the hair thus preventing fungal invasion of newly forming cells.

## **6. PHARMACEUTICAL PARTICULARS**

### **6.1 List of excipients**

Sodium starch glycollate

Povidone K30

Lactose monohydrate

### **6.2 Incompatibilities**

None known.

### **6.3 Shelf life**

Shelf-life of the veterinary medicinal product as packaged for sale: 2 years

### **6.4. Special precautions for storage**

Do not store above 25°C.

Protect from light.

Store away from food, drink and animal feedstuffs

Add to feed immediately prior to administration. Discard any remaining medicated feed.

### **6.5 Nature and composition of immediate packaging**

500g pots and 1kg and 2.5kg buckets. One 5ml scoop.

### **6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products**

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

**7. MARKETING AUTHORISATION HOLDER**

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

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

Vm 08007/4022

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

10<sup>th</sup> November 1989/10<sup>th</sup> November 2004

**10. DATE OF REVISION OF THE TEXT**

June 2008