SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Grisol V Powder 7.5% w/w oral powder

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance:
Griseofulvin 7.5% w/w

For a full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Oral powder.
An off white to pale grey powder.

4. CLINICAL PARTICULARS

Target species

Horses

4.2 Indications for use, specifying the target species

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.

4.3 Contra-indications

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.

4.4 Special warnings for each target species

None

4.5 Special precautions for use

(i) 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.

(ii) 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 high doses of griseofulvin with food has been reported to be hepatotoxic in cats and induce hepatomas in mice and thyroid tumours in rats, but not hamsters. The clinical significance of these findings for man is not known.

Store away from food, drink and animal feedingstuffs. Hands and exposed skin should be washed after use.

4.6 Adverse reactions (frequency and seriousness)

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.

See sections 4.7 and 4.10.

4.7 Use during pregnancy, lactation or lay

Only be used in mares which are not pregnant or lactating.

Griseofulvin may be teratogenic.

4.8 Interaction with other medicinal products and other forms of interaction

The efficacy of this product may be impaired if used concurrently with substances such as phenylbutazone and sedatives which induce drug-metabolising enzymes.

4.9 Amounts to be administered and administration route

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.

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

Possible side effects include gastrointestinal disorder, anaemia, leucopenia, granulocytopenia, ataxia, hypersensitivity reactions, vasodilation and its clinical signs, proteinuria and nephrosis. In the event of an overdose treatment should be symptomatic.

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

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 1μg/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.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Calcium carbonate

6.2 Incompatibilities

None known

6.3 Shelf life

Shelf life of 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 feedingstuffs.

6.5 Nature and composition of immediate packaging

500g polypropylene tubs (with sealed polyethylene bags inside) closed with high density polyethylene lid (screw fit) supplied with a blue polystyrene 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
Vetoquinol House
Great Slade
Buckingham Industrial Park
Buckingham
MK18 1PA

8. MARKETING AUTHORISATION NUMBER(S)

Vm 08007/4032
VPA 10966/29/1

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

UK: 11 January 1993/11 January 2003
Ireland: 17th December 2004

10. DATE OF REVISION OF THE TEXT

November 2008