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

Not authorised for use in horses intended for human consumption.

5. PHARMACOLOGICAL PROPERTIES

ATC vet code: QD01BA01

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

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8. MARKETING AUTHORISATION NUMBER

Vm: 08007/4022

9. DATE OF FIRST AUTHORISATION

Date: 10th November 1989

10. DATE OF REVISION OF THE TEXT

Date: August 201


12 August 2014