SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Norofulvin 7.5% w/w Granules for Top Dressing Use

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substance:

Each gram contains 7.5% w/w of Griseofulvin

Excipients:
For a full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Granules for Top Dressing Use
White to off-white 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 Contraindications

None

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. Norofulvin Granules should be mixed 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 group 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

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

4.6 Adverse reactions (frequency and seriousness)

Long term administration of high doses of griseofulvin with food has been reported to be hepatotoxic in cats and to induce hepatomas in mice and thyroid tumours in rats but not hamsters. The clinical significance of these findings in the target species is not known.
Griseofulvin may be teratogenic (see 4.5)

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 known.

4.9 Amounts to be administered and administration route

Administer orally, by addition to and mixing in the feed ration.

The recommended dose rate is 10 mg griseofulvin per kg bodyweight daily for seven consecutive days. This is achieved by administering 10g Norofulvin Granules per 75 kg 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

Pharmacotherapeutic group: Antifungals for dermatological use, Antifungals for systemic use.

ATC Vet Code: QD01BA01

5.1 Pharmacodynamic properties

Griseofulvin is a 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 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 separately from animal feeds.
Add to feed immediately before administration.
Discard any remaining medicated feed.

6.5 Nature and composition of immediate packaging

Available in the following pack sizes;

- 500g and 3.5 kg polyethylene bags in polypropylene containers closed with push fit polypropylene lids. Supplied with 5g plastic scoop.
- 1 kg polyethylene bags in high density polyethylene buckets closed with a polypropylene push fit lids. Supplied with 5 g plastic scoop.
- 20 g polyethylene/aluminium foil/paper laminate heat sealed sachets.

Not all pack sizes may be marketed.

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

Any unused product or waste material should be disposed of in accordance with national requirements.

7. MARKETING AUTHORISATION HOLDER

Norbrook Laboratories Limited
Station Works
Camlough Road
Newry
Co. Down
BT35 6JP
Northern Ireland

8. MARKETING AUTHORISATION NUMBER

Vm 02000/4084

9. DATE OF FIRST AUTHORISATION

Date: 20 July 1987

10. DATE OF REVISION OF THE TEXT

Date: December 2014

APPROVED T. NASH **10/12/14**