SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Norofulvin 33.3% w/w Equine Oral Paste.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substance:
Norofulvin Equine Paste contains Griseofulvin 33.3% w/w

Excipients:

Methyl Parahydroxybenzoate 0.15% w/w

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

- Oral Paste.
- A white, viscous paste for oral administration

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.

4.3 Contraindications

Other systemic fungal infections including *Candida albicans* and *Aspergillus* spp. do not respond to Griseofulvin therapy.
Do not use on pregnant mares.

4.4 Special Warnings for each target species

No special warnings.

4.5 Special precautions for use

i) Special precautions for use in animals

None.

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

The product must not be handled by women of child-bearing potential.

Protective gloves should be worn when using this product.

Take care to avoid skin contact. In the case of skin contact wash affected area thoroughly. If irritation occurs/persists seek medical advice.

Take care to avoid accidental eye contact. In case of accidental eye contact flush thoroughly with clean water and seek medical advice.

Ingestion: If accidentally swallowed, seek medical attention and show product label and/or pack leaflet to the doctor.

Wash hands thoroughly after using this product.

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)

None.

4.7 Use during pregnancy, lactation or lay

Not for use in pregnant mares

4.8 Interaction with other medicinal products and other forms of interaction

Substances such as phenylbutazone and sedatives which induce drug metabolising enzymes may result in impaired efficacy.

4.9 Amounts to be administered and administration route

There are 15 x 150kg doses marked on the syringe

For oral administration, using a dial-a-dose syringe, at a dose rate of 10 mg Griseofulvin/kg daily for seven consecutive days. Each complete

turn of the dial delivers 4.61 g of product (1.5g Griseofulvin). The following is the dosage regimen recommended for each of the seven days dosing period.

Liveweight	Dose (grams of Griseofulvin)	No. of Dial Turns
150kg	1.5	1
300kg	3.0	2
450kg	4.5	3
600kg	6.0	4

Where animal's weight is other than the above weights, ¼, ½ and ¾ turns of the dial may be given as appropriate.
Prophylactic administration of the medication is advised for in-contact animals only**.**

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 systematic use.

ATC Vet Code: QD01BA01

5.1 Pharmacodynamic properties

Griseofulvin is a fungistatic 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

Methyl Parahydroxybenzoate
Sorbitan Monolaurate
Polysorbate 20
Propylene Glycol
Glycerol

6.2 Incompatibilities

None known.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and composition of immediate packaging

Marketed in a 70g multidose dial a dose oral syringe comprising of a white opaquue high density polyethylene barrel and white opaque low density polyethylene plunger closed with white opaque low density polyethylene push fit cap.

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 02000/4055

9. DATE OF FIRST AUTHORISATION

Date: 10 May 1985

10. DATE OF REVISION OF THE TEXT

Date: December 2014

APPROVED T. NASH 10/12/14