

PARTICULARS TO APPEAR ON THE OUTER AND IMMEDIATE PACKAGE
{Carton and Syringe Label}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Norofulvin 33.3% w/w Equine Oral Paste

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

A white viscous paste containing Griseofulvin 33.3% w/w

3. PHARMACEUTICAL FORM

Oral paste

4. PACKAGE SIZE

70 g dial-a-dose syringe

5. TARGET SPECIES

Horse

6. INDICATION(S)

Norofulvin is an oral antifungal antibiotic effective in the treatment of ringworm in horses caused by *Trichophyton* spp and *Microsporum* spp.

Carton ONLY: After absorption from the gastrointestinal tract the antifungal antibiotic is concentrated in the newly formed keratin enabling the cells of the skin and hair to resist fungal attack.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

There are 15 x 150kg doses marked on the syringe

Dosage: 10 mg Griseofulvin /kg daily for 7 days.

Liveweight	Dose (Expressed as no. of dial turns)
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Horses

150 kg

1

300 kg

2

450 kg

3

600 kg

4

Carton ONLY: 15 turns per syringe

Syringe Label ONLY: IMPORTANT: Further information: See package leaflet.

8. WITHDRAWAL PERIOD

Not authorised for use in horses intended for human consumption.

9. SPECIAL WARNING(S), IF NECESSARY

Not for use in pregnant mares. Other systemic fungal infections including *Candida albicans* and *Aspergillus* spp do not respond to Griseofulvin therapy. The efficacy of this product may be impaired as a result of concurrent administration of substances such as phenylbutazone and sedatives which induce drug metabolising enzymes.

Operator Warnings:

The product must not be handled by women of child bearing potential. Protective gloves should be worn when using the product. Take care to avoid skin contact. In the case of skin contact wash affected area thoroughly. If irritation 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 package 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.

10. EXPIRY DATE

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C. Keep the container in the outer carton.

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority.

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE [Distribution category]

POM-V

For animal treatment only. To be supplied only on veterinary prescription

14. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

KEEP OUT OF THE SIGHT AND REACH OF CHILDREN

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Norbrook Laboratories Limited,
Newry, Co. Down, Northern Ireland.

16. MARKETING AUTHORISATION NUMBER(S)

Vm 02000/4055

17. MANUFACTURER'S BATCH NUMBER

PACKAGE LEAFLET FOR:

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Norbrook Laboratories Limited,
Newry, Co. Down, Northern Ireland.

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Norofulvin 33.3% w/w Equine Oral Paste

3. STATEMENT OF THE ACTIVE SUBSTANCE (S) AND OTHER INGREDIENTS

A white viscous paste containing 33.3% w/w Griseofulvin in a 70g dial-a-dose syringe.

4. INDICATION(S)

Norofulvin Equine Paste is an oral antifungal antibiotic effective in the treatment of ringworm in horses caused by *Trichophyton* and *Microsporum* spp. After absorption from the gastrointestinal tract the antifungal antibiotic is concentrated in the newly formed keratin enabling the cells of the skin and hair to resist fungal attack.

5. CONTRAINDICATIONS

Concurrent administration of substances such as Phenylbutazone and sedatives which induce drugmetabolizing enzymes may result in impaired efficacy of Norofulvin. Norofulvin Equine Paste 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.

6. ADVERSE REACTIONS

If you notice any serious effects or other effects not mentioned in this leaflet please inform your veterinary surgeon.

7. TARGET SPECIES

Horses

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

There are 15 x 150kg doses marked on the syringe. For oral administration using a dial-a-dose syringe, 10 mg Griseofulvin/kg bodyweight daily for 7 consecutive days. The following is the dosing regimen recommended for each of the 7 days dosing period.

LIVEWEIGHT DOSE (Expressed as no. of dial turns)

Horses

150 kg	1
300 kg	2
450 kg	3
600 kg	4

9. ADVICE ON CORRECT ADMINISTRATION

Where the animals weight is other than above weight, 1/4, 1/2, or 3/4 turns of the dial may be given where appropriate.

PROPHYLACTIC ADMINISTRATION OF NOROFULVIN EQUINE PASTE IS ADVISABLE FOR IN-CONTACT ANIMALS ONLY.

10. WITHDRAWAL PERIOD(S)

Not authorised for use in horses intended for human consumption.

11. SPECIAL STORAGE PRECAUTIONS

Do not store above 25°C.

Keep out of the reach and sight of children.

Keep syringe in outer carton.

12. SPECIAL WARNING(S)

Norofulvin is not recommended for use in pregnant mares. Other systemic fungal infections including *Candida albicans* and *Aspergillus* spp do not respond to Griseofulvin therapy.

Operator Warnings:

The product must not be handled by women of child bearing potential. Protective gloves should be worn when using the product. Take care to avoid skin contact. In the case of skin contact wash affected area thoroughly. If irritation 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 package 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.

For Animal Treatment Only

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

Package Quantities:

70 g dial-a-dose syringe.

Vm 02000/4055

POM-V To be supplied only on veterinary prescription

FURTHER INFORMATION:

The normal seven day course is recommended. Stables occupied by infected horses should be thoroughly disinfected and cleaned; all equipment used during the treatment should also be cleaned and disinfected. These measures will minimize the risk of cross infection.

Approved: 10/01/2018

