

IRISH MEDICINES BOARD ACT 1995

MEDICINAL PRODUCTS(LICENSING AND SALE)REGULATIONS, 1998

(S.I. No.142 of 1998)

10996/072/001A
Case No: 7002392

The Irish Medicines Board in exercise of the powers conferred on it by the above mentioned Regulations hereby grants to

Intervet Ireland Limited

Magna Drive, Magna Business Park, Citywest Road, Dublin 24, Ireland

an authorisation, subject to the provisions of the said Regulations, in respect of the product

Mycophyt 10%w/w Pdr for Cutaneous Susp

The particulars of which are set out in Part I and Part II of the attached Schedule. The authorisation is also subject to the general conditions as may be specified in the said Regulations as listed on the reverse of this document.

This authorisation, unless previously revoked, shall continue in force from **15/12/2006** until .

Signed on behalf of the Irish Medicines Board

A person authorised in that behalf by the said Board.

Part II

Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Mycophyt 10% w/w Powder for Cutaneous Suspension

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each g contains:

Active Substance

Natamycin 100 mg

For a full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Powder for the preparation of a cutaneous suspension in water, (containing 0.01% natamycin after reconstitution) for spraying or sponging.

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle and horses

4.2 Indications for use, specifying the target species

For the treatment of dermatophytosis in cattle and horses, for example ringworm caused by *Trichophyton verrucosum* in cattle and *Trichophyton* and *Microsporum* infections in horses.

Treatment of stables, immediate surroundings, harness, brushes etc is recommended to prevent re-infection.

4.3 Contraindications

Do not use in animals with known hypersensitivity to the active ingredient.

Do not mix Mycophyt suspension with other topical medications.

4.4 Special warnings for each target species

It is recommended that treatment takes place in the stable or cowshed; if the animals are outside they should be treated in the evening.

Previous treatment with greasy preparations prevents Mycophyt from gaining access to infected areas; where this has occurred, 14 days should be allowed to elapse before Mycophyt treatment is started.

Avoid exposure of the animal to direct sunlight during and for a few hours after treatment.

4.5 Special precautions for use

Special precaution(s) for use in animals

Care should be taken that the water used for reconstitution is neither excessively hard, nor contains large quantities of chlorine.

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

None

4.6 Adverse reactions (frequency and seriousness)

None

4.7 Use during pregnancy, lactation or lay

No special precautions

4.8 Interaction with other medicinal products and other forms of interaction

It is not advisable to mix Mycophyt suspension with other topical medications.

4.9 Amounts to be administered and administration route

Preparing the suspension:

Care should be taken that the water used for reconstitution is neither excessively hard, nor contains large quantities of chlorine. Cleanse buckets and spraying equipment thoroughly before use as natamycin may lose activity by contact with chemicals. Carefully add water to the bottle of Mycophyt until 2/3 full. Replace cap and shake vigorously. Add the suspension to a thoroughly cleansed bucket and make up to a volume of 2 litres with water for 2 g Mycophyt or 10 litres for 10g Mycophyt. Where possible use galvanised or plastic buckets as natamycin is sensitive to heavy metals such as copper.

Stir the final suspension well just before use. Use the suspension within 24 hours of preparation.

Administration:

The suspension can be applied by spraying or sponging. In mass treatment of cattle spraying may be preferable. For the individual treatment of horses and cattle, sponging down the affected area is advised.

In mass treatment, the entire body surface of all animals (affected and non-affected) should be sprayed in order to prevent any spread from affected animals not yet showing visible lesions. Particular attention needs to be paid to preferential sites of infection, such as head (inner side of the external ear), neck, loins and base of tail (in the horse also the saddle and harness area). A suitable spray apparatus would be the ASL horticultural spray or a knapsack type spray. An aerosol generator should not be used. In order to ward off infection/re-infection, brushes, saddle, harness etc. should be immersed in the final suspension.

Note. Even on spraying, Mycophyt is not harmful to man or animal. The area around the eyes can be treated without special precautions.

About 750 ml final suspension should be used for each calf and about 1 litre for each cow or horse. One 2 g container of Mycophyt is sufficient for a single treatment of 3 calves of 6-9 months or 2 adult cows or horses. One 10 g container of Mycophyt is sufficient for a single treatment of 15 calves of 6-9 months or 10 adult cows or horses. Treatment should be repeated four to five days later. If after 14 days affected areas do not show any visible improvement, treatment should be repeated at 14 day intervals.

If no improvement is seen, or the condition worsens, after four treatments consult your veterinary surgeon.

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

No specific treatment or antidote recommended.

4.11 Withdrawal Period(s)

Cattle: Meat/Milk: Nil. Animals may be slaughtered for human consumption immediately after treatment.
Horses: Edible tissues from slaughtered animals: 28 days.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Mycophyt is a preparation of natamycin, an antifungal antibiotic, indicated for the treatment of dermatophytosis in cattle and horses.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium Laurel sulfate
Colloidal Anhydrous Silica
Lactose Monohydrate
Citric Acid

6.2 Incompatibilities

None known but product should not be mixed with other products.

6.3 Shelf-life

Shelf life: 24 months
Reconstituted product should be used immediately.

6.4 Special precautions for storage

Do not store above 25°C. Protect from light.

6.5 Nature and composition of immediate packaging

Amber Glass Type III (Ph.Eur) with white lacquered aluminium screw caps, in bottles of 2 g or 10 g.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials

Unused product or waste material should be disposed of in accordance with current practice for pharmaceutical waste under national waste disposal regulations.

7 MARKETING AUTHORISATION HOLDER

Intervet Ireland Ltd
Magna Drive
Magna Business Park
Citywest Road
Dublin 24

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10996/72/1

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

1st October 2004.