

IRISH MEDICINES BOARD ACT 1995

EUROPEAN COMMUNITIES (ANIMAL REMEDIES) REGULATIONS 2007

(S.I. No. 144 of 2007)

VPA: **10007/039/001**
Case No: 7002447

The Irish Medicines Board in exercise of the powers conferred on it by Animal Remedies Regulations (S.I. No. 144 of 2007) hereby grants to:

Boehringer Ingelheim Ltd

Ellesfield Avenue, Bracknell, Berkshire RG12 8YS, England

an authorisation, subject to the provisions of the said Regulations and the general conditions of the attached authorisation, in respect of the Veterinary Medicinal Product:

Insol Dermatophyton suspension for injection for horses, dogs and cats

The particulars of which are set out in Part 1 and Part 2 of the said Schedule. The authorisation is also subject to any special conditions as may be specified in the said Schedule.

The authorisation, unless previously revoked, shall continue in force from **23/02/2007**.

Signed on behalf of the Irish Medicines Board

A person authorised in that behalf by the said Board.

(NOTE: From this date of effect, this authorisation replaces any previous authorisation in respect of this product which is now null and void.)

Part II

Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Insol Dermatophyton suspension for injection for horses, dogs and cats

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml of inactivated vaccine contains:

Prior to inactivation:

Minimum: 55 x 10⁶ microconidia of each of the following fungal strains in equal quantity to stimulate at least satisfactory protection in the rabbit potency test.

Maximum: 65 x 10⁶ microconidia of each of the following fungal strains in equal quantity:

- *Trichophyton verrucosum*, strain no. 410
- *Trichophyton mentagrophytes*, strain no. 1032
- *Trichophyton sarkisovii*, strain no. 551
- *Trichophyton equinum*, strain no. 381
- *Microsporum canis*, strain no. 1393
- *Microsporum canis var. distortum*, strain no. 120
- *Microsporum canis var. obesum*, strain no. 1311
- *Microsporum gypseum*, strain no. 59

Final product:

Minimum: 50 x 10⁶ microconidia (corresponding to 6.25 x 10⁶ microconidia of each strain).

Maximum: 60 x 10⁶ microconidia (corresponding to 7.50 x 10⁶ microconidia of each strain).

Thiomersal: 0.04 mg in a glucose meat extract suspension.

For a full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Yellowish brown suspension for injection

4 CLINICAL PARTICULARS

4.1 Target Species

Horses from five months of age, dogs from six weeks of age and cats from ten weeks of age.

4.2 Indications for use, specifying the target species

For active immunisation of horses, dogs and cats against dermatophytosis caused by *Trichophyton verrucosum*, *Trichophyton mentagrophytes*, *Trichophyton sarkisovii*, *Trichophyton equinum*, *Microsporum canis* and *Microsporum gypseum* for the purpose of reducing the risk of a clinical infection due to these fungal species, and as a therapeutic measure for accelerating the healing of clinically visible skin changes in animals infected with dermatophytosis caused by these fungal species.

Onset of protection occurs by five weeks after first vaccination and lasts for at least nine months.

4.3 Contraindications

Do not use in animals with fever and/or symptoms of an infectious disease other than dermatophytosis.

Do not vaccinate stressed animals.

Do not administer subcutaneously.

4.4 Special warnings for each target species

None

4.5 Special precautions for use

Special precautions for use in animals

Where animals are incubating the disease at the time of vaccination, the lesions may still break out although these will usually heal within 2 to 4 weeks after the second injection.

Since dermatophytosis spores which cannot be reached by vaccination may also be present on the surface of the animal's coat, the risk of zoonosis cannot be eliminated without additional measures like environmental disinfection. For this reason, and also to reduce the infection pressure, it is recommended that long-haired animals be shaved of their hair. Therefore, it is also recommended that animals in direct or indirect contact with infected animals should also be vaccinated.

In order to reduce the general infection pressure, the surrounding area and utensils (e.g. cleaning equipment) should be cleaned and disinfected.

Experience in the field has shown that, particularly in the case of stocks of thoroughbred cats, in which increased infection pressure is to be expected, reduced efficacy can occur or a tendency to recurrence can be observed.

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

Avoid accidental contact with skin. In case the vaccine is accidentally spilled onto the skin, rinse with water.

Accidental self-injection may lead to mild transient swelling at the injection site or to severe side effects. In the case of accidental self-injection, seek medical advice immediately and show the package insert or the label to the physician.

4.6 Adverse reactions (frequency and seriousness)

After injection in horse, local reactions in the form of swellings (max. 4 cm diameter) that may be slightly painful, can be observed in 3 % of the vaccinated animals. Systemic reactions in the form of fever, apathy or loss of appetite can be observed in 1.3 % of the cases. Both local and systemic effects will resolve within eight days, without any additional treatment. In some rare cases larger painful swellings (about 15 cm) have been reported. In very rare cases allergic reactions may occur in horses with hypersensitivity. If such signs occur symptomatic treatment is recommended.

After injection in dogs, local reactions in the form of swellings sometimes accompanied with pain, can be observed in 2.6 % of the vaccinated animals. Systemic reactions in the form of slight fever and or apathy can be observed in 0.3 % of the cases. Both local and systemic effects will resolve within five days, without any additional treatment.

After injection in cats, local reactions in the form of swellings sometimes accompanied with pain, can be observed in 0.2 % of the vaccinated animals. No systemic reactions were reported in cats. Local reactions will resolve within five days without any additional treatment.

A possible worsening in clinical signs of dermatophytosis (erythema, oedema transudation at the diseased skin sites) after therapeutic vaccination can be observed. If such clinical signs occur, symptomatic treatment is recommended.

4.7 Use during pregnancy, lactation or lay

Do not use during pregnancy and lactation.

4.8 Interaction with other medicinal products and other forms of interaction

No information is available on the safety and efficacy from the concurrent use of this vaccine with any other. It is therefore recommended that no other vaccine should be administered within 14 days before or after vaccination with this product.

4.9 Amounts to be administered and administration route

Shake well before use!

Prophylactic vaccination:

Basic vaccination: two deep injections should be given intramuscularly on alternate sides of the body, 14 days apart.

Re-vaccination: every nine months: two deep injections should be given intramuscularly on alternate sides of the body, 14 days apart.

Treatment:

Two deep injections should be given intramuscularly on alternate sides of the body, 14 days apart. If there is still no clearly identifiable improvement in the skin and hair lesions of animals infected with dermatophytosis two weeks after a second injection, a third injection is recommended. The recommendation of the third administration in horses is based on practical experience and on extrapolation of efficacy data from cats and dogs.

Recommended dose:

Species:	Bodyweight:	Dose in ml:
<u>Horses:</u>	under 400 kg	0.3 ml
	over 400 kg	0.5 ml
<u>Dogs:</u>	up to 10 kg	0.3 ml
	over 10 kg	0.5 ml
<u>Cats:</u>	over 1.0 kg	1.0 ml

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

The incidence of the undesirable effects as mentioned under 4.6 could be increased.

4.11 Withdrawal Period(s)

Zero days.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

The administration of the vaccine stimulates the development of immunity against dermatophytosis caused by *Trichophyton verrucosum*, *Trichophyton mentagrophytes*, *Trichophyton sarkisovii*, *Trichophyton equinum*, *Microsporum canis* and *Microsporum gypseum* in horses, dogs and cats.

The immunity is mainly a cell-mediated immune response.

ATC Vet code: QI05AQ (horse)

ATC Vet code QI07AQ (dog)

ATC Vet code QI06AQ (cat)

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Thiomersal

Glucose

Meat extract

Water for Injection in bulk

6.2 Incompatibilities

Do not mix with any other vaccine or immunological product.

6.3 Shelf-life

Shelf-life of the veterinary medicinal product: 3 years

Shelf life after first opening the immediate packaging: 14 days. Discard any product remaining in the container at this time. Avoid introduction of contamination.

6.4 Special precautions for storage

Store and transport refrigerated (2°C to +8°C), including the storage period after first opening.

Do not freeze.

Keep the glass vial in the outer carton.

6.5 Nature and composition of immediate packaging

Glass vial of type I filled with 2 ml or 5 ml, with bromobutyl rubber stopper and aluminium sealing caps. Pack sizes: 2 ml, 5 x 2 ml and 5 ml. Not all package sizes may be marketed.

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

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

7 MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Ltd.
Ellesfield Avenue,
Bracknell,
RG12 8YS,
U.K.

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10007/39/1

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

23rd February 2007

10 DATE OF REVISION OF THE TEXT

None