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:

Active substance

Prior to inactivation:

Minimum:
55 x 10^6 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 10^6 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
- *Nannizzia gypsea*, strain no. 59

Final product:
Minimum: 50 x 10^6 microconidia (corresponding to 6.25 x 10^6 microconidia of each strain).

Maximum: 60 x 10^6 microconidia (corresponding to 7.50 x 10^6 microconidia of each strain).

Excipients:

Thiomersal: 0.04 mg

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 5 months of age, dogs from 6 weeks of age and cats from 10 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 *Nannizzia gypsea* 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 5 weeks after first vaccination and lasts for at least 9 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 veterinary medicinal 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 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 8 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 animals with hypersensitivity. If such clinical 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 5 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 5 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 vaccines should be administered within 14 days before or after vaccination with the product.

4.9 Amounts to be administered and administration route

Shake well before use!

Prophylactic vaccination:
Basic vaccination: 2 deep injections should be given intramuscularly on alternate sides of the body, 14 days apart.

Re-vaccination: every 9 months: 2 deep injections should be given intramuscularly on alternate sides of the body, 14 days apart.

Treatment:
Two (2) 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 2 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:*
Horses:	under 400 kg	0.3 ml
	over 400 kg	0.5 ml
Dogs:	up to 10 kg	0.3 ml
	over 10 kg	0.5 ml
Cats:	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. 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 *Nannizzia gypsea* 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
Yeast extract
Water for Injection

6.2 Incompatibilities

Do not mix with any other vaccine or immunological product.

6.3 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale:	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 - 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 product or waste materials derived from the use of such products

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

7. MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Vetmedica GmbH
55216 Ingelheim
Germany

8. MARKETING AUTHORISATION NUMBER(S)

to be completed

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: to be completed
Date of renewal of authorisation: to be completed

10. DATE OF REVISION OF THE TEXT

to be completed after renewal date

PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable.