## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Insol® Trichophyton suspension for injection for cattle

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml of inactivated vaccine contains:

**Active substance**

Minimum:
17 x $10^6$ microconidia of each of the following fungal strains:

- *Trichophyton verrucosum*, strain no. 410
- *Trichophyton mentagrophytes*, strain no. 1032
- *Trichophyton sarkisovii*, strain no. 551

**Excipient:**

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

Cattle from one month of age.

### 4.2 Indications for use, specifying the target species

Active immunisation of cattle against trichophytosis caused by *Trichophyton verrucosum*, *Trichophyton mentagrophytes* and/or *Trichophyton sarkisovii* and as an aid in the treatment of cattle infected by trichophytosis caused by these fungal species.

The stimulated immunity belongs mainly to the cell-mediated-type and lasts at least for 12 months.

### 4.3 Contraindications

None.

### 4.4 Special warnings for each target species

Animals with fever and/or symptoms of an infectious disease other than trichophytosis and animals which are still under the influence of corticosteroids should not be vaccinated. Animals under four weeks of age should not be vaccinated.

Do not vaccinate stressed animals, particularly animals for which a new straw-bedding has been freshly prepared.

In rare cases infections with the subspecies *Trichopyhton verrucosum ochraceum* have been observed in practice which have a non-typical development including persistent signs of trichophytosis, multiple, deep and partly hemorrhagic skin erosions. In these cases a delayed or no efficacy must be expected after vaccination. Therapeutic success can be obtained with a repeated vaccination and possibly simultaneous topical treatment (e.g. rinses) with appropriate products.

## 4.5 Special precautions for use

**Special precautions for use in animals**
In the case of animals which are in the incubation phase at the time of vaccination, the disease can still break out in spite of the vaccination. However, the skin lesions heal 2 - 4 weeks after the second injection.

**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. 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)

Slight swelling can occur at the injection site (mostly after accidental subcutaneous injection) which clears with no adverse symptoms.

In exceptional cases (ca. 0.05 %) shock reactions in form of dyspnea, pulmonal oedema, reddish foam around the mouth and nose and heavy transpiration can occur (death can occur in ca. 0.01 % of the vaccinated animals). In such cases symptomatic treatment including administration of adrenalin, glucocorticoids and antihistamines, possibly together with a dose of calcium, is indicated.

## 4.7 Use during pregnancy, lactation or lay

The vaccination can be carried out at any stage of pregnancy. To date no effect on milk output has been observed.

## 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!

The vaccination dose is:

| | |
|---|---|
| for cattle with less than 70 kg bodyweight: | 2.5 ml |
| for cattle with more than 70 kg bodyweight: | 5.0 ml |

Both for prophylaxis and for therapy two intramuscular injections with a 14-day interval are required. The injections should be given on alternate sides of the body. To maintain the vaccine protection after prophylactic or therapeutic administration repeat vaccinations should be carried out at yearly intervals.

Subcutaneous injection is to be avoided.

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

Can lead to slight local intolerance reactions.

### 4.11 Withdrawal period(s)

Meat: 3 days
Milk: 0 days

## 5. IMMUNOLOGICAL PROPERTIES

The administration of the vaccine stimulates the development of immunity in cattle against trichophytosis caused by *Trichophyton verrucosum*, *Trichophyton mentagrophytes* and *Trichophyton sarkisovii*.

The vaccine-strains are of animal origin: *Trichophyton verrucosum*, strain 410, was isolated on a reindeer, *Trichophyton mentagrophytes*, strain 1032, on a horse and *Trichophyton sarkisovii*, strain 551, on a camel. These vaccine-strains are highly specific to cattle.

ATC Vet code: QI02AB

## 6. PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Thiomersal
Glucose
Meat 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 container: | 14 days if stored at between +2°C to +8°C. 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).
Do not freeze.
Keep the container in the outer carton.

### 6.5 Nature and composition of immediate packaging

50 ml, 100 ml or 250 ml glass vials of Type II glass, sealed with bromobutyl rubber stoppers and crimp-on aluminium caps in cardboard boxes.

Not all pack 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

to be completed by OPU

## 8. MARKETING AUTHORISATION NUMBER(S)

to be completed by OPU

## 9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

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

## 10. DATE OF REVISION OF THE TEXT

November 2008

## PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable.