

# Summary of Product Characteristics

## 1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Imaverol 100 mg/ml Concentrate for Cutaneous Emulsion

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

### **Active Substance per ml**

Enilconazole 100 mg

For a full list of excipients, see section 6.1

## 3 PHARMACEUTICAL FORM

Cutaneous emulsion

Brown-yellow, clear viscous solution

## 4 CLINICAL PARTICULARS

### 4.1 Target Species

Cattle

Horse

Dog

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

For the treatment of dermatomycoses in cattle, horses and dogs induced by the following pathogenic fungi:

*Trichophyton verrucosum*

*Trichophyton mentagrophytes*

*Trichophyton equinum*

*Microsporum canis*

*Microsporum gypseum*

### 4.3 Contraindications

None.

### 4.4 Special warnings for each target species

None.

### 4.5 Special precautions for use

#### **Special precautions for use in animals**

The solution must be diluted before use.

For external use only.

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

Wear suitable protective clothing including impermeable rubber gloves and safety glasses.

If the concentrated solution comes into contact with the skin, remove any contaminated clothing immediately and wash skin generously with soap and water. In the event of accidental eye exposure, flush eye thoroughly with running water. If irritation persists, seek medical attention. In the event of accidental ingestion, flush mouth with plenty of running water and seek medical advice.

Wash hands after use.

#### **4.6 Adverse reactions (frequency and seriousness)**

None known.

#### **4.7 Use during pregnancy, lactation or lay**

Laboratory studies in rodents have not produced evidence of embryotoxic or teratogenic effects. This product may be given to pregnant and lactating animals.

#### **4.8 Interaction with other medicinal products and other forms of interactions**

None known.

#### **4.9 Amounts to be administered and administration route**

For topical use only.  
To be prepared and administered in adequately ventilated surroundings.

The concentrated Imaverol solution should be diluted by adding 1 part to 50 parts warm water to provide a 2 mg/ml emulsion.

Dermatophytes will extend into the hair follicles. Possible crusts must therefore be removed with a hard brush which has been soaked in the diluted Imaverol emulsion.

It is highly recommended that the animal is sprayed entirely at the first treatment so as to reach the subclinical lesions as well.

*Cattle:* depending on the nature of the lesions, cattle should be treated 3 to 4 times at 3-day intervals. The animals should either be washed with the diluted emulsion or the emulsion should be applied to them with a sprayer or high-pressure cleaning unit.

*Horses:* the lesions and surrounding skin should be washed with the diluted emulsion 4 times at 3-day intervals.

*Dogs:* the animals should be washed with the diluted emulsion 4 times at 3-day intervals. While doing this, one should rub thoroughly in the direction opposite to the hair growth to make sure that the skin is thoroughly wet. For the same reason, it is recommended that long haired dogs be clipped before treatment.

Alternatively dogs may be dipped thoroughly in a bath containing the prepared emulsion.

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

None known.  
Enilconazole as a 2 mg/ml emulsion is well tolerated. Supportive treatment as required.

#### **4.11 Withdrawal period(s)**

Cattle: Meat - zero days Cattle: Milk - zero hours  
Horse: Meat - zero days

### **5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES**

Pharmacotherapeutic group: Antifungals for topical use - imidazole and triazole derivatives.  
ATCvet code: QD01AC90

#### **5.1 Pharmacodynamic properties**

Enilconazole is a synthetic broad-spectrum antimycotic with a high activity against most of the common dermatophytes and various other fungi and yeasts.

It is a selective inhibitor of ergosterol biosynthesis, an essential component of the cell membrane of fungi and yeasts. This results in irreversible changes which are the origin of the fungicidal effect.

## **5.2 Pharmacokinetic particulars**

The systemic availability after topical administration of enilconazole in animals is very low. An extensive first-pass metabolism has been demonstrated after oral administration. Tissue residues are almost non-existent and, relatively, are highest in the liver. Depletion from tissues and plasma occurs with a half-life of about 12 to 16 hours in cattle.

Enilconazole is extensively metabolised and the main excretion routes are urine and faeces. Excretion in the milk from cattle is very limited.

## **6 PHARMACEUTICAL PARTICULARS**

### **6.1 List of excipients**

Sorbitan Monolaurate Polysorbate 20

### **6.2 Major incompatibilities**

None known.

### **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 : 3 months.

Shelf life after dilution according to directions: 6 weeks.

### **6.4 Special precautions for storage**

Do not store above 25°C.

Keep the bottle in the outer carton.

Keep in an adequately ventilated area.

### **6.5 Nature and composition of immediate packaging**

i) 100 ml pack size:

Container: amber Type III glass bottle containing 100ml of concentrate.

Closure: tamper evident and child resistant polypropylene screw cap lines with LDPE

Dosing device: polypropylene measuring cup.

ii) 1 litre pack size:

Container: white, high density polyethylene bottle with transparent window containing 1 litre of concentrate.

Closure: white high density polyethylene screw cap and seal insert lined with polyethylene

Dosing device: low density polyethylene measuring cup

Not all pack sizes may be marketed.

### **6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products**

Do not allow the product to contaminate streams or water supplies.

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

**7 MARKETING AUTHORISATION HOLDER**

AUDEVARD  
42/46 Rue Mederic  
92110 Clichy  
France

**8 MARKETING AUTHORISATION NUMBER(S)**

VPA10481/001/001

**9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

Date of first authorisation: 01 October 1989

Date of last renewal: 30 September 2009

**10 DATE OF REVISION OF THE TEXT**

February 2019