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

i. Special precautions for use in animals

The solution must be diluted before use.
For external use only.

ii. 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 interaction

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 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 properties

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 Monolaureate
Polysorbate 20

6.2 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 100 ml of concentrate.
Closure:	tamper evident and child resistant polypropylene screw cap lined 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

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 Médéric
92110 Clichy
France

8. MARKETING AUTHORISATION NUMBER

Vm 44684/4003

9. DATE OF FIRST AUTHORISATION

13 August 1985

10. DATE OF REVISION OF THE TEXT

January 2020

Approved: 07 January 2020