1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Imaverol 100 mg/ml Concentrate for Cutaneous Emulsion

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active Substance:
Enilconazole 100 mg

Excipients:

Qualitative composition of excipients and other constituents
Sorbitan Monolaurate
Polysorbate 20

Brown-yellow, clear viscous solution.

3. CLINICAL INFORMATION

3.1 Target species

Cattle, horses, dogs.

3.2 Indications for use for each 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

3.3 Contraindications

None.

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:

Diluted veterinary medicinal product is very well tolerated.
Unlike the concentrated emulsion, the diluted emulsion is not irritating to the skin or to the eyes, and can be licked by the treated animals without side effects.
For external use only.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Personal protective equipment consisting of impermeable rubber gloves and safety glasses should be worn when handling the veterinary medicinal product.
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 immediately and show the package leaflet or the label to the physician.
Wash hands after use.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse reactions

None known.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:

Laboratory studies in rodents have not produced any evidence of embryotoxic or teratogenic effects. Can be used during pregnancy and lactation.

3.8 Interaction with other medicinal products and other forms of interaction

None known.

3.9 Administration routes and dosage

Cutaneous use.

To be prepared and administered in adequately ventilated surroundings.

The concentrated veterinary medicinal product 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 veterinary medicinal product.

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.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

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

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance.

Not applicable.

3.12 Withdrawal periods

Cattle:
Meat and offal: Zero days.
Milk: Zero hours.

Horses:
Meat and offal: Zero days.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code:

QD01AC90

4.2 Pharmacodynamics

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 membrance of fungi and yeasts. This results in irreversible changes which are the origin of the fungicidal effect.

4.3 Pharmacokinetics

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.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

None known.

5.2 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.

5.3 Special precautions for storage

Do not store above 25 °C.
Keep the bottle in the outer carton.
Keep in an adequately ventilated area.

5.4 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.

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

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Audevard

7. MARKETING AUTHORISATION NUMBER(S)

VPA10481/001/001

8. DATE OF FIRST AUTHORISATION

01/10/1989

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

25/03/2026

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).