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Date: Monday, February 23, 2026 13:09

Audevard

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Imaverol 100 mg/ml Concentrate for Cutaneous Emulsion

Species: Cattle, Dogs, Horses and other equidae

Therapeutic indication:Pharmaceuticals: Antimicrobials: Topical preparations: Skin, **Pharmaceuticals: Antimicrobials:** Antifungal products

Active ingredient: Enilconazole

Product: Imaverol 100 mg/ml Concentrate for Cutaneous Emulsion

Product index: Imaverol 100 mg/ml Concentrate for Cutaneous Emulsion

Cattle - milk: Zero hours

Cattle - meat: Zero hours

Withdrawal notes: Horses: meat - Zero days

Incorporating:

Qualitative and quantitative composition

Active Substance:

Enilconazole

Pharmaceutical form

Cutaneous emulsion.

Brown-yellow, clear, viscous solution.

Clinical particulars

Target Species

Cattle, horse, dog

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 metagrophytes

Trichophyton equinum

Microsporum canis

Microsporum gypseum

Contraindications

None.

Special warnings for each target species

None.

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.

Adverse reactions (frequency and seriousness)

None known.

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.

Interaction with other medicinal products and other forms of interaction

None known.

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 mgl/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 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.

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

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

Withdrawal Period(s)

Cattle: Meat - zero days

Cattle: Milk - zero hours

Horse: Meat - zero days

Pharmacological particulars

Pharmacotherapeutic group

Antifungals for topical use - imidazole and triazole derivatives.

ATCvet code: QD01AC90

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 or ergosterol biosynthesis, an essential component of the cell membrane of fungi and yeasts. This results in irreversible changes which are the origin of the fungi and yeasts. This results in irreversible changes which are the origin of the fungicide effect.

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 resides are almost non-existent and, relatively, are highest in the liver. Depletion from tissues and plasm 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.

Pharmaceutical particulars

List of Excipients

Sorbitan Monolaureate

Polysorbate 20

Incompatibilities

None know.

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

Special precautions for storage

Do not store above 25°C

Keep the bottle in the outer carton

Keep in adequately ventilated area

Nature and composition of immediate packaging

100ml 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

1 litre pack size

Container:	white, high density polyethylene bottle with transparent window containing 1 litre of conce
Closure:	white high desnity polyethylene screw cap and seal insert lined with polyethylene
Dosing device:	low density polyethylene measuring cup

Not all pack sizes may be marketed.

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 regulatory authority.

Marketing Authorisation Holder (if different from distributor)

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Marketing Authorisation Number

UK: 44684/4003

Significant changes

Date of the first authorisation or date of renewal

13 August 1985

Date of revision of the text

January 2020

Any other information

Nil

Legal category

Legal category:POM-VPS

GTIN

GTIN description:IMAVEROL 100ml bottle

GTIN:03515652020001