

ANNEX III
LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARTON

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Imaverol 100 mg/ml Concentrate for Cutaneous Emulsion

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains: 100 mg enilconazole

3. PHARMACEUTICAL FORM

Concentrate for Cutaneous Emulsion

4. PACKAGE SIZE

100 ml

5. TARGET SPECIES

Cattle, horses and dogs
<pictures of cattle, horse and dog>

6. INDICATION(S)

For cutaneous use only
For the control of dermatomycoses in cattle, horses and dogs

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Dosage, method and route of administration:
Read the package leaflet before use.
DILUTE 1:50 WITH WARM WATER BEFORE USE.

8. WITHDRAWAL PERIOD(S)

Withdrawal period(s):
Cattle/Horse: meat - zero days.
Cattle: milk - zero hours.

9. SPECIAL WARNING(S), IF NECESSARY

10. EXPIRY DATE

Shelf-life after first opening the container: 3 months

Date to be discarded:

Shelf-life after dilution according to directions: 6 weeks

Use by end: {month/year}

11. SPECIAL STORAGE CONDITIONS

Keep the bottle in the outer carton.

Do not store above 25 °C.

Keep in an adequately ventilated area.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal:

Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority. Do not allow the product to contaminate streams or waterways.

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

FOR ANIMAL TREATMENT ONLY. FOR EXTERNAL USE ONLY.

UK only

POM-VPS

To be supplied only on veterinary
prescription
Vm 44684/4003

14. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

KEEP OUT OF THE SIGHT AND REACH OF CHILDREN.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Audevard
37-39 rue de Neuilly
92110, Clichy
France

16. MARKETING AUTHORISATION NUMBER

Vm 44684/4003

17. MANUFACTURER'S BATCH NUMBER
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Batch No: {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

100ml BOTTLE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Imaverol 100 mg/ml Concentrate for Cutaneous Emulsion

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains: 100 mg enilconazole

3. PHARMACEUTICAL FORM

Concentrate for Cutaneous Emulsion

4. PACKAGE SIZE

100 ml

5. TARGET SPECIES

Cattle, horses and dogs

6. INDICATION(S)

For the control of dermatomycoses in cattle, horses and dogs

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For indications, dosage, administration, warnings, precautions and disposal advice:
Read package leaflet before use.

For cutaneous use only

DILUTE 1:50 WITH WARM WATER BEFORE USE

8. WITHDRAWAL PERIOD(S)

Withdrawal period(s):

Cattle/Horse: meat - zero days.

Cattle: milk - zero hours.

9. SPECIAL WARNING(S), IF NECESSARY

Do not allow the product to contaminate streams or waterways.

10. EXPIRY DATE

Use by end: {month/year}

11. SPECIAL STORAGE CONDITIONS

Keep the bottle in the outer carton.
Do not store above 25 °C.
Keep in an adequately ventilated area.
Shelf-life after first opening the container: 3 months.
Shelf-life after dilution according to directions: 6 weeks.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

FOR ANIMAL TREATMENT ONLY. FOR EXTERNAL USE ONLY.

UK: POM-VPS

To be supplied only on veterinary prescription.

14. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

KEEP OUT OF THE SIGHT AND REACH OF CHILDREN.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Audevard
37-39 rue de Neuilly
92110, Clichy
France

16. MARKETING AUTHORISATION NUMBER

Vm 44684/4003

17. MANUFACTURER'S BATCH NUMBER

Batch {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET:
Imaverol 100 mg/ml Concentrate for Cutaneous Emulsion

**1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER
AND OF THE MANUFACTURING AUTHORISATION HOLDER
RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT**

Marketing authorisation holder:

Audevard
37-39 rue de Neuilly
92110, Clichy
France

Manufacturer responsible for batch release:

Lusomedicamenta
Sociedade Técnica Farmacêutica, S.A
Estrada Consiglieri Pedroso, n°66, 69-B,
Queluz de Baixo
Barcarena, 2730-055
Portugal

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Imaverol 100 mg/ml Concentrate for Cutaneous Emulsion

**3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER
INGREDIENT(S)**

Each ml contains: 100 mg enilconazole

4. INDICATION(S)

Imaverol is an antifungal medicine that works against fungi that cause skin infections in cattle, horses and dogs, caused by fungi such as:

Trichophyton verrucosum

Trichophyton mentagrophytes

Trichophyton equinum

Microsporum canis

Microsporum gypseum

5. CONTRAINDICATIONS

None known.

6. ADVERSE REACTIONS

None known.

In rare occasions, digestive signs (anorexia, salivation, vomiting) and nervous signs (ataxia, lethargy) were observed.

Skin disorders (pruritus, alopecia) have been reported very rarely based on post-marketing safety experience.

The frequency of adverse reactions is defined using the following convention:

- Very common (more than 1 in 10 animals displaying adverse reactions during the course of treatment)
- Common (more than 1 but less than 10 animals in 100 animals)
- Uncommon (more than 1 but less than 10 animals in 1,000 animals)
- Rare (more than 1 but less than 10 animals in 10,000 animals)
- Very rare (less than 1 animals in 10,000 animals, including isolated reports).

If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Cattle, horses and dogs.
For animal treatment only.

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

Route and method of administration

For application on to the skin (cutaneous use).

Dosage

Dilute the concentrated Imaverol by adding 1 part to 50 parts warm water.
Dilute and use in well ventilated surroundings.

Treatment: The fungi will get into the hair follicles, therefore, remove any crusts with a hard brush, which has been soaked in the diluted Imaverol emulsion.
It is best to spray the animal all over for the first treatment so that all lesions are treated, even those that cannot be seen.

Cattle

Treat 3 to 4 times at 3 day intervals, depending on the nature of the lesions.
Wash the animals with the diluted emulsion or use a sprayer or high-pressure cleaning unit to apply the emulsion.

Horse

Wash the lesions and surrounding skin with the diluted emulsion 4 times, at 3 day intervals.

Dog

Wash the animals with the diluted emulsion 4 times, at 3 day intervals.
While doing this, rub thoroughly in the opposite direction to the hair growth to make sure that the skin is thoroughly wet.
For the same reason, it is recommended to clip long-haired dogs before treatment.
Alternatively, dogs may be dipped thoroughly in a bath containing the prepared emulsion, care should be taken not to get the product in the eyes, nose or mouth.

9. ADVICE ON CORRECT ADMINISTRATION

10. WITHDRAWAL PERIOD(S)

Cattle/Horse: meat - zero days

Cattle: milk - zero hours

11. SPECIAL STORAGE PRECAUTIONS

Keep the bottle in the outer carton.

Keep out of the sight and reach of children.

For animal treatment only.

Do not store above 25 °C.

Keep in an adequately ventilated area.

Do not use after the expiry date which is stated on the label and carton. The date refers to the last day of that month.

Shelf-life after first opening the container: 3 months.

When the container is broached (opened) for the first time, work out the date on which any remaining product should be discarded and write this date in the space provided on the carton.

Shelf-life after dilution according to directions: 6 weeks.

12. SPECIAL WARNING(S)

Special precautions for use in animals

The solution must be diluted before use.

Where possible, do not allow the animal to lick itself during treatment. Take care to avoid the animal inhaling the product or getting it into the eyes, nose or mouth.

Special precautions for 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.

Accidental ingestion of the product by animals may lead to adverse reactions (see section 6).

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

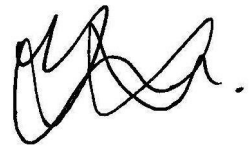
Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority.
Do not allow the product to contaminate streams or water supplies.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

November 2022

15. OTHER INFORMATION

Pack sizes: 100 ml, 1 Litre.
Not all pack sizes may be marketed.

A handwritten signature in black ink, consisting of several loops and a final flourish.

Approved: 30 November 2022