ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

50 ML, 100 ML or 250 ML / CARDBOARD BOX

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Diatrim 200 mg/ml + 40 mg/ml solution for injection

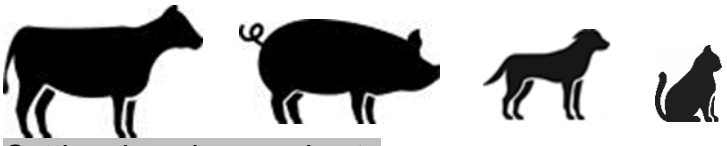
2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:
Sulfadiazine 200 mg
Trimethoprim 40 mg

3. PACKAGE SIZE

50 ml, 100 ml, 250 ml

4. TARGET SPECIES



Cattle, pigs, dogs and cats.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Subcutaneous (dogs, cats), intramuscular or slow intravenous use (cattle, pigs).

7. WITHDRAWAL PERIODS

Withdrawal periods:
Cattle:
Meat and offal: 12 days
Milk: 48 hours

Pigs:
Meat and offal: 20 days

8. EXPIRY DATE

Exp: {mm/yyyy}
Shelf life after first opening the immediate packaging: 28 days.

Once broached, use by: _____/_____/_____

9. SPECIAL STORAGE PRECAUTIONS

Do not store in a refrigerator after broaching.

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

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

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Eurovet Animal Health B.V.

14. MARKETING AUTHORISATION NUMBERS

Vm 16849/3011

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

50 ML, 100 ML or 250 ML / GLASS VIAL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Diatrim 200 mg/ml + 40 mg/ml, solution for injection

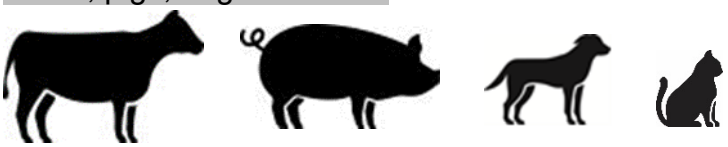
2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:

Sulfadiazine	200 mg
Trimethoprim	40 mg

3. TARGET SPECIES

Cattle, pigs, dogs and cats.



4. ROUTES OF ADMINISTRATION

Dogs, cats: s.c.
Cattle, pigs: i.m., i.v. (slow)

5. WITHDRAWAL PERIODS

Withdrawal periods:
Cattle:
Meat and offal: 12 days
Milk: 48 hours

Pigs:
Meat and offal: 20 days

6. EXPIRY DATE

Exp: {mmh/yyyy}
Once broached, use within 28 days. Use by _____/_____/_____

7. SPECIAL STORAGE PRECAUTIONS

Do not store in a refrigerator after broaching.

8. NAME OF THE MARKETING AUTHORISATION HOLDER

Eurovet Animal Health B.V.

9. BATCH NUMBER

Lot {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Diatrim 200 mg/ml + 40 mg/ml, solution for injection for cattle, pigs, dogs and cats.

2. Composition

Each ml contains:

Active substances:

Sulfadiazine	200 mg
Trimethoprim	40 mg

Excipient:

N-methyl pyrrolidone	510 mg

Clear, greenish yellow to brownish yellow solution, practically free from particles.

3. Target species

Cattle, pigs, dogs and cats.

4. Indications for use

Treatment of infections caused by, or associated with, organisms sensitive to the trimethoprim-sulfadiazine combination.

5. Contraindications

Do not use in cases of hypersensitivity to the active substances or to any of the excipients.
Do not use in animals with severe liver or renal damage or blood dyscrasias.
Do not use in case of reduced water intake or losses of body fluid.

6. Special warnings

Special precautions for safe use in the target species:
Use of the veterinary medicinal product should be based on susceptibility testing of the bacteria isolated from the animal. If this is not possible, therapy should be based on local (regional, farm level) epidemiological information about susceptibility of the target bacteria.
Use of the veterinary medicinal product deviating from the instructions given in the product leaflet may increase the prevalence of bacteria resistant to the veterinary

medicinal product and may decrease the effectiveness of treatment with other antimicrobials or classes of antimicrobials due to the potential for cross-resistance. Official, national and regional antimicrobial policies should be taken into account when the veterinary medicinal product is used.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
The veterinary medicinal product may cause an allergic reaction in people sensitised to sulfonamides.
People with known hypersensitivity to sulfonamides should avoid contact with the veterinary
medicinal product.

Take care to avoid self-injection. In case of accidental self-injection or I-if you develop symptoms
following exposure, such as a skin rash, you should seek medical advice immediately and show the
package leaflet or the label to the physician. Swelling of the face, lips or eyes or difficulty in breathing
are more serious symptoms and require urgent medical attention.

Wash hands after use.

This veterinary medicinal product may cause skin and eye irritation. Avoid contact with skin or eyes.
In case of accidental contact, rinse the affected area immediately with plenty of water. If symptoms
persist, seek medical advice.

Laboratory studies in rabbits and rats with the excipient N-methyl pyrrolidone have shown evidence of foetotoxic effects. Women of childbearing age, pregnant women or women suspected of being pregnant should use the veterinary medicinal product with serious caution to avoid accidental self-injection.

Pregnancy and lactation:
The safety of the veterinary medicinal product has not been established in cattle, pigs, dogs and cats during pregnancy, lactation or in animals intended for breeding. Laboratory studies in rabbits and rats with the excipient N-methyl pyrrolidone have shown evidence of foetotoxic effects.
Use only according to the benefit-risk assessment by the responsible veterinarian.

Interaction with other medicinal products and other forms of interaction:
Local anaesthetics from the group of para-aminobenzoic acid esters (procaine, tetracaine) can locally inhibit the effect of sulfonamides.
Do not combine with other veterinary medicinal products.

Overdose:
None known.

Special restrictions for use and special conditions for use:
Not applicable.

Major incompatibilities:
In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

7. Adverse events

Cattle, pigs, dogs and cats:

Rare (1 to 10 animals / 10,000 animals treated):	Anaphylactic shock [a,b]

[a] Potentially fatal.
[b] Following administration of potentiated sulphonamide preparations, mostly after intravenous injection. For intravenous administration the veterinary medicinal product should be warmed to body temperature and injected slowly over as long a period as is reasonably practical. At the first sign of intolerance the injection should be interrupted and shock treatment initiated.

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system: {national system details}.

8. Dosage for each species, routes and method of administration

For intramuscular, intravenous or subcutaneous use.
To ensure a correct dosage, the body weight of animals to be treated should be determined as accurately as possible.

Cattle and pigs:
The recommended dose rate is 2.5 mg trimethoprim / 12.5 mg sulfadiazine per kilogram body weight (1 ml veterinary medicinal product per 16 kg body weight) by intramuscular or slow intravenous injection, once daily until 2 days after symptoms resolve up to a maximum of 5 days The maximum intramuscular volume of injection per injection site is 5 ml for pigs and 15 ml in cattle. The veterinary medicinal product may be administered by intravenous injection when blood levels of trimethoprim and sulfadiazine are required more rapidly.

Dogs and cats:
The recommended dose rate is 5 mg trimethoprim / 25 mg sulfadiazine per kilogram body weight (1 ml veterinary medicinal product per 8 kg body weight), by subcutaneous injection only, once daily until 2 days after symptoms resolve up to a

maximum of 5 days. The recommended injection site in dogs is the loose skin at the top of the neck.

The closures must not be punctured more than 40 times.

9. Advice on correct administration

For intravenous administration the product should be warmed to body temperature and injected slowly over as long a period as is reasonably practical. At the first sign of intolerance the injection should be interrupted and shock treatment initiated. Intravenous administration should be used with extreme caution and only if therapeutically justified.

10. Withdrawal periods

Cattle:
Meat and offal: 12 days
Milk: 48 hours

Pigs:
Meat and offal: 20 days

11. Special storage precautions

Keep out of the sight and reach of children.
Do not store in a refrigerator after broaching Do not use this veterinary medicinal product after the expiry date which is stated on the label and carton after Exp. The expiry date refers to the last day of that month.
Shelf life after first opening the immediate packaging: 28 days.

12. Special precautions for disposal

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 applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

Pack sizes: 50 ml, 100 ml or 250 ml colourless glass type II vial with fluoropolymer coated chlorobutyl stopper type I stopper secured with an aluminium cap.
1 vial in a cardboard box.

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

December 2023

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

16. Contact details

Marketing authorisation holder and contact details to report suspected adverse reactions:

Manufacturer responsible for batch release:
Eurovet Animal Health B.V.
Handelsweg 25
5531 AE Bladel
The Netherlands

Local representatives and contact details to report suspected adverse reactions:

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

17. Other information

Environmental properties
Trimethoprim is persistent in soils.

Approved: 18 May 2024

Gavin Hall