LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

50 ml / 100 ml – carton box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. STATEMENT OF ACTIVE SUBSTANCES

1 ml solution contains:
Active substances:

Sulfadiazine	200 mg
Trimethoprim	40 mg

3. PHARMACEUTICAL FORM

Solution for injection.

4. PACKAGE SIZE

50 ml, 100 ml

5. TARGET SPECIES

Cattle, pigs, dogs and cats.

6. INDICATION(S)

7. METHOD AND ROUTES OF ADMINISTRATION

For subcutaneous (dogs, cats), intramuscular or slow intravenous injection (cattle, pigs).

8. WITHDRAWAL PERIOD(S)

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

Pig:
Meat and offal: 20 days

9. SPECIAL WARNINGS, IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP: {month/year}
Shelf life after first opening the immediate packaging: 28 days.
Once broached, use by: _____/_____/_____

11. SPECIAL STORAGE CONDITIONS

Do not store in a refrigerator after broaching.

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

Disposal: Read package leaflet.

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

For animal treatment only.
To be supplied only on veterinary prescription. *To be completed nationally*

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

Eurovet Animal Health BV
Handelsweg 25
5531 AE Bladel
The Netherlands

16. MARKETING AUTHORISATION NUMBER

Vm 16849/4059

17. MANUFACTURER'S BATCH NUMBER

Lot: {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

50 ml / 100 ml - label

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. STATEMENT OF ACTIVE SUBSTANCES

1 ml solution contains:
Active substances:

Sulfadiazine	200 mg
Trimethoprim	40 mg

3. PHARMACEUTICAL FORM

Solution for injection.

4. PACKAGE SIZE

50 ml, 100 ml

5. TARGET SPECIES

Cattle, pigs, dogs and cats.

6. INDICATION(S)

7. METHOD AND ROUTES OF ADMINISTRATION

For subcutaneous (dogs, cats), intramuscular or slow intravenous injection (cattle, pigs).

8. WITHDRAWAL PERIOD(S)

Withdrawal periods:
Cattle:

Meat and offal:	12 days
Milk:	48 hours

Pig:
Meat and offal: 20 days

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP: {month/year}
Once broached, use by _____/_____/_____

11. SPECIAL STORAGE CONDITIONS

Do not store in a refrigerator after broaching.

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.
To be supplied only on veterinary prescription. *To be completed nationally*

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Eurovet Animal Health BV
Handelsweg 25
5531 AE Bladel
The Netherlands

16. MARKETING AUTHORISATION NUMBER

Vm 16849/4059

17. MANUFACTURER'S BATCH NUMBER

Lot: {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET FOR:
Diatrim 200 mg/ml + 40 mg/ml solution for injection

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

Marketing authorisation holder and manufacturer responsible for batch release:
Eurovet Animal Health BV
Handelsweg 25
5531 AE Bladel
The Netherlands

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

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

1 ml solution contains:
Active substances:

Sulfadiazine	200 mg
Trimethoprim	40 mg

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

4. INDICATION(S)

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

5. CONTRAINDICATIONS

Do not use in case 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. ADVERSE REACTIONS

Anaphylactic shock (potentially fatal) has been observed on rare occasions (more than 1 but less than 10 animals in 10,000 animals treated) following administration of potentiated sulphonamide preparations, mostly after intravenous injection.

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 inform your veterinary surgeon.

7. TARGET SPECIES

Cattle, pigs, dogs and cats.

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 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 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 PERIOD

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

Pig:
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 WARNINGS

Special precautions for use in animals:

Use of the 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 product deviating from the instructions given in the product leaflet may increase the prevalence of bacteria resistant to the 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 product is used.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

- The 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.
- The excipient N-methylpyrrolidone (NMP) is a suspected human teratogen; therefore, women of child-bearing age must be very careful to avoid exposure via spillage onto the skin or accidental self-injection when administering the product. If you are pregnant, think you may be pregnant or are attempting to conceive, you should not administer the product."
- If you develop symptoms following exposure such as a skin rash, you should seek medical advice and show the doctor this warning. Swelling of the face, lips or eyes or difficulty with breathing are more serious symptoms and require urgent medical attention.
- This product may cause skin and eye irritation.
- Avoid contact with skin or eyes.
- In case of skin or eye contact, wash exposed area with plenty of clean water. If symptoms persist, seek medical advice.
- In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.
- Wash hands after use.

Use during pregnancy or lactation:
Can be safely administered to lactating animals. The product contains N-methylpyrrolidone, which is considered to be a reproductive toxicant. As the relevant

studies have not been performed, use in pregnant cattle, pigs, dogs, and cats should be avoided.

Interaction with other medicinal products and other forms of interaction:
Local anesthetics 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 (symptoms, emergency procedures, antidotes):
None known.

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

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

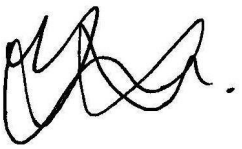
14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

Pack sizes: 50 ml, 100 ml.
Not all pack sizes may be marketed.

Trimethoprim is persistent in soils

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



Approved: 14 June 2022