<PARTICULARS TO APPEAR ON THE OUTER PACKAGE>

{Cardboard box}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Enrotron 25 mg/ml oral solution for cattle
Enrofloxacin

2. STATEMENT OF ACTIVE SUBSTANCES

1 ml contains:
Active substance:
Enrofloxacin 25.0 mg

3. PHARMACEUTICAL FORM

4. PACKAGE SIZES

100 ml
12 x 100 ml
6 x 500 ml

5. TARGET SPECIES

Cattle (calves)

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For direct oral use or with water, milk, milk replacer or electrolyte solution.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Withdrawal period:
Meat and offal: 7 days

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Once opened, use by…
Shelf life after first opening the immediate packaging: 3 months
Shelf life after dilution or reconstitution according to directions: 24 hours

11. SPECIAL STORAGE CONDITIONS

Keep the bottle tightly closed.
After dilution, do not expose to direct daylight.

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

Disposal: read the package leaflet before use.

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.

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

Marketing authorisation holder

aniMedica GmbH
Im Südfeld 9
48308 Senden-Bösensell
Germany

Distributor

Forte Healthcare
Cougar Lane
Naul
Co. Dublin
Ireland

16. MARKETING AUTHORISATION NUMBER

Vm 24745/4021

17. MANUFACTURER'S BATCH NUMBER

<Batch> <Lot> <BN> {number}

<PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE>

{Bottle}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Enrotron 25 mg/ml oral solution for cattle
Enrofloxacin

2. STATEMENT OF ACTIVE SUBSTANCES

1 ml contains:
Active substance:
Enrofloxacin 25.0 mg

3. PHARMACEUTICAL FORM

4. PACKAGE SIZES

100 ml
500 ml

5. TARGET SPECIES

Cattle (calves)

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For direct oral use or with water, milk, milk replacer or electrolyte solution.

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Withdrawal period:
Meat and offal: 7 days

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Once opened, use by…
Shelf life after first opening the immediate packaging: 3 months
Shelf life after dilution or reconstitution according to directions: 24 hours

11. SPECIAL STORAGE CONDITIONS

Keep the bottle tightly closed.
After dilution, do not expose to direct daylight.

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.

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

Marketing authorisation holder
aniMedica GmbH
Im Südfeld 9
48308 Senden-Bösensell
Germany

Distributor

Forte Healthcare
Cougar Lane
Naul
Co. Dublin
Ireland

16. MARKETING AUTHORISATION NUMBER

Vm 24745/4021

17. MANUFACTURER'S BATCH NUMBER

<Batch> <Lot> <BN> {number}

PACKAGE LEAFLET

Enrotron 25 mg/ml oral solution for cattle

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

Marketing authorisation holder

aniMedica GmbH
Im Südfeld 9
48308 Senden-Bösensell
Germany

Manufacturers responsible for batch release

aniMedica GmbH
Im Südfeld 9
48308 Senden-Bösensell
Germany

Industrial Veterinaria, S.A.
Esmeralda 19
Esplugues de Llobregat
08950 Barcelona
Spain

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Enrotron 25 mg/ml oral solution for cattle
Enrofloxacin

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

1 ml contains:
Active substance:
Enrofloxacin 25.0 mg
Excipients:
Benzyl alcohol (E-1519) 14.0 mg

Clear slightly yellow solution.

4. INDICATION(S)

Treatment of infections of the respiratory and alimentary tract caused by enrofloxacin-sensitive microorganisms.

In particular:

- Treatment of neonatal diarrhoea and septicaemia caused by enrofloxacin-sensitive *E. coli.*
- Treatment of respiratory infections caused by enrofloxacin-sensitive *Pasteurella multocida*, *Mannheimia haemolytica* and *Mycoplasma bovis.*

To be used where clinical experience and/or sensitivity testing indicates enrofloxacin as the drug of choice.

5. CONTRAINDICATIONS

Do not use in case of confirmed or suspected resistance to quinolones, since a high degree of cross resistance between enrofloxacin and other (fluoro)quinolones does exist.
Do not use in cases of hypersensitivity to the active substance, to other (fluoro)quinolones or to any of the excipients.
Do not use in cases of disturbances to the growth of cartilage and/or during injury to the locomotory system particularly if functionally loaded or body weight loaded joints are affected. Do not use for prophylaxis.

6. ADVERSE REACTIONS

Gastrointestinal disturbances may rarely occur (more than 1 but less than 10 animals in 10000 animals).
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.
Alternatively you can report via your national reporting system {national system details}.

7. TARGET SPECIES

Cattle (calves)

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

For oral administration.

Dosage

2.5 mg enrofloxacin per kg bodyweight (equivalent to 5 ml per 50 kg bodyweight) daily for 3 to 5 days.
In case of complicated infections: 5 mg per kg bodyweight (equivalent to 10 ml per 50 kg bodyweight) daily for 5 days.
To ensure a correct dosage body weight should be determined as accurately as possible to avoid underdosing.
The intake of the reconstituted veterinary medicinal product depends on the clinical condition of the animals. In order to obtain the correct dosage the concentration of enrofloxacin has to be adjusted accordingly.

Medicated drinking water should be replaced every 24 hours.

Administration route
For direct oral use or with water, milk, milk replacer or electrolyte solution.

9. ADVICE ON CORRECT ADMINISTRATION

Not applicable.

10. WITHDRAWAL PERIOD

Meat and offal: 7 days

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Keep the bottle tightly closed.
After dilution, do not expose to direct daylight.
Shelf life after first opening the immediate packaging: 3 months
Shelf life after dilution or reconstitution according to directions: 24 hours
Do not use this veterinary medicinal product after the expiry date which is stated on the label.
The expiry date refers to the last day of that month.

12. SPECIAL WARNING(S)

Special warnings for each target species

None.

Special precautions for use in animals

Official and local antimicrobial policies should be taken into account when the product is used.
Fluoroquinolones should be reserved for the treatment of clinical conditions which have responded poorly, or are expected to respond poorly, to other classes of antimicrobials.
Susceptibility testing should be performed before treatment is initiated.
Use of the veterinary medicinal product deviating from instructions given in the SPC may increase the prevalence of bacteria resistant to fluoroquinolones and may decrease the effectiveness of treatment with other quinolones due to the potential for cross resistance.
During the period of rapid growth, enrofloxacin may affect articular cartilage.
Calves which only receive roughage should not be treated orally but by means of injection.

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

People with known hypersensitivity to (fluoro)quinolones should avoid contact with the veterinary medicinal product.
Avoid skin and eye contact.

Direct contact with the skin should be avoided because of sensitisation, possible hypersensitivity reactions and contact dermatitis.
Wear gloves for this purpose.
Rinse any splashes from skin or eyes immediately with water.
Wash hands and exposed skin after use.
Do not smoke, eat or drink whilst using the veterinary medicinal product.
Interaction with other medicinal products and other forms of interaction
Concurrent administration of enrofloxacin with other antimicrobials, tetracyclines and macrolide antibiotics may result in antagonistic effects. Absorption of enrofloxacin may be reduced if the product is administered together with substances containing magnesium or aluminium.
Do not combine enrofloxacin with steroidal anti-inflammatory products.
Overdose (symptoms, emergency procedures, antidotes)
Do not exceed the recommended treatment dose. In accidental overdose there is no antidote and treatment should be symptomatic.
Incompatibilities
In 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 product should be disposed of in accordance with local / national requirements.
Medicines should not be disposed of via wastewater or household waste.
Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

{DD/MM/YYYY}

15. OTHER INFORMATION

Pack sizes: 1 x 100 ml; 12 x 100 ml; 1 x 500 ml; 6 x 500 ml
Not all pack sizes may be marketed.
To be supplied only on veterinary prescription.
MA-No.: XXXXXX

B. COMBINED LABEL

Full information of package leaflet and label are provided on the 500 ml bottle.
This package size is therefore marketed without secondary packaging.

Combined Label

Enrotron 25 mg/ml oral solution for cattle

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

Marketing authorisation holder

aniMedica GmbH
Im Südfeld 9
48308 Senden-Bösensell
Germany

Manufacturers responsible for batch release

aniMedica GmbH
Im Südfeld 9
48308 Senden-Bösensell
Germany

Industrial Veterinaria, S.A.
Esmeralda 19
Esplugues de Llobregat
08950 Barcelona
Spain

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Enrotron 25 mg/ml oral solution for cattle
Enrofloxacin

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

1 ml contains:
Active substance:
Enrofloxacin 25.0 mg
Excipients:
Benzyl alcohol (E-1519) 14.0 mg

Clear slightly yellow solution.

4. PHARMACEUTICAL FORM

Oral solution

5. PACKAGE SIZE

Pack size:
500 ml

6. INDICATION(S)

Treatment of infections of the respiratory and alimentary tract caused by enrofloxacin-sensitive microorganisms.
In particular:

- Treatment of neonatal diarrhoea and septicaemia caused by enrofloxacin-sensitive *E. coli.*
- Treatment of respiratory infections caused by enrofloxacin-sensitive *Pasteurella multocida*, *Mannheimia haemolytica* and *Mycoplasma bovis.*

To be used where clinical experience and/or sensitivity testing indicates enrofloxacin as the drug of choice.

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Do not use in cases of hypersensitivity to the active substance, to other (fluoro)quinolones or to any of the excipients.
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Cattle (calves)

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To ensure a correct dosage body weight should be determined as accurately as possible to avoid underdosing.
The intake of the reconstituted veterinary medicinal product depends on the clinical condition of the animals. In order to obtain the correct dosage the concentration of enrofloxacin has to be adjusted accordingly.
Medicated drinking water should be replaced every 24 hours.

Administration route

For direct oral use or with water, milk, milk replacer or electrolyte solution.

11. ADVICE ON CORRECT ADMINISTRATION

Not applicable.

12. WITHDRAWAL PERIOD

Meat and offal: 7 days

13. SPECIAL STORAGE PRECAUTIONS

Keep the bottle tightly closed.
After dilution, do not expose to direct daylight.

14. SPECIAL WARNING(S)

Special warnings for each target species

None.

Special precautions for use in animals

Official and local antimicrobial policies should be taken into account when the product is used.
Fluoroquinolones should be reserved for the treatment of clinical conditions which have responded poorly, or are expected to respond poorly, to other classes of antimicrobials.
Susceptibility testing should be performed before treatment is initiated.
Use of the veterinary medicinal product deviating from instructions given in the SPC may increase the prevalence of bacteria resistant to fluoroquinolones and may decrease the effectiveness of treatment with other quinolones due to the potential for cross resistance.
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Special precautions to be taken by the person administering the veterinary medicinal product to animals

People with known hypersensitivity to (fluoro)quinolones should avoid contact with the veterinary medicinal product.
Avoid skin and eye contact.
Direct contact with the skin should be avoided because of sensitisation, possible hypersensitivity reactions and contact dermatitis.

Wear gloves for this purpose.
Rinse any splashes from skin or eyes immediately with water.
Wash hands and exposed skin after use.
Do not smoke, eat or drink whilst using the veterinary medicinal product.

Interaction with other medicinal products and other forms of interaction
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Do not combine enrofloxacin with steroidal anti-inflammatory products.
Overdose (symptoms, emergency procedures, antidotes), if necessary
Do not exceed the recommended treatment dose. In accidental overdose there is no antidote and treatment should be symptomatic.

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Medicines should not be disposed of via wastewater or household waste. Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

16. DATE ON WHICH THE LABEL WAS LAST APPROVED

{DD/MM/YYYY}

17. OTHER INFORMATION

Pack sizes:
1 x 100 ml; 12 x 100 ml; 1 x 500 ml; 6 x 500 ml
Not all pack sizes may be marketed.

18. 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.

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

Keep out of the sight and reach of children.

20. EXPIRY DATE

EXP {month/year}
Once opened, use by…
Shelf life after first opening the immediate packaging: 3 months
Shelf life after dilution or reconstitution according to directions: 24 hours
Do not use this veterinary medicinal product after the expiry date which is stated on the label.
The expiry date refers to the last day of that month.

21. MARKETING AUTHORISATION NUMBER

Marketing authorisation number(s):
MA-No.: 24745/4021

22. MANUFACTURER'S BATCH NUMBER

Manufacturer's batch number:
<Batch>

Approved: 25 July 2018