<PARTICULARS TO APPEAR ON THE OUTER PACKAGE>

{Cardboard Box}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Enrotron 5 mg/ml oral solution for pigs
Enrofloxacin

2. STATEMENT OF ACTIVE SUBSTANCES

1 ml contains:
Active substance:
Enrofloxacin 5.0 mg

3. PHARMACEUTICAL FORM

Oral solution

4. PACKAGE SIZES

100 ml
250 ml
12 x 100 ml
6 x 250 ml

5. TARGET SPECIES

Pigs (piglets)

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

The veterinary medicinal product is administered orally directly into the mouth of the animals using the dispenser.
The dosing pump of the dispenser delivers 1 ml per pump stroke.
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

11. SPECIAL STORAGE CONDITIONS

Keep the bottle tightly closed.
Discard unused material.

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 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 Ltd
Cougar Lane
Naul
Co. Dublin
Ireland

16. MARKETING AUTHORISATION NUMBER

Vm 24745/4020

17. MANUFACTURER'S BATCH NUMBER

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

<PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE>

{Bottle 100 ml, 250 ml}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Enrotron 5 mg/ml oral solution for pigs
Enrofloxacin

2. STATEMENT OF ACTIVE SUBSTANCES

1 ml contains:
Active substance:
Enrofloxacin 5.0 mg

3. PHARMACEUTICAL FORM

Oral solution

4. PACKAGE SIZES

100 ml
250 ml

5. TARGET SPECIES

Pigs (piglets)

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

The veterinary medicinal product is administered orally directly into the mouth of the animals using the dispenser.
The dosing pump of the dispenser delivers 1 ml per pump stroke.
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

11. SPECIAL STORAGE CONDITIONS

Keep the bottle tightly closed.
Discard unused material.

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

[Not requested on the immediate label]

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 Ltd
Cougar Lane
Naul
Co. Dublin
Ireland

16. MARKETING AUTHORISATION NUMBER

Vm 24745/4020

17. MANUFACTURER'S BATCH NUMBER

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

PACKAGE LEAFLET

Enrotron 5 mg/ml oral solution for pigs

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 5 mg/ml oral solution for pigs
Enrofloxacin

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

1 ml contains:
Active substance:
Enrofloxacin 5.0 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* spp.
- Enzootic pneumonia

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

5. CONTRAINDICATIONS

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.

6. ADVERSE REACTIONS

None known.
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

Pigs (piglets)

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

For oral administration.

Dosage

1.7 mg enrofloxacin per kg bodyweight daily for 3 to 5 days equivalent to 1 ml per 3 kg bodyweight.
To ensure a correct dosage body weight should be determined as accurately as possible to avoid underdosing.

Administration route

The veterinary medicinal product is administered orally directly into the mouth of the animals using the dispenser.
The dosing pump of the dispenser delivers 1 ml per pump stroke.

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.
Shelf life after first opening the immediate packaging*:* 3 months
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.
Discard unused material.

12. SPECIAL WARNING(S)

Special precautions for use in animals
Official and local antimicrobial policies should be taken into account when the product is used.
Do not use in case of confirmed or suspected resistance to quinolones, since a high degree of cross resistance between enrofloxacin and other quinolones does exist.
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.
Do not use for prophylaxis.
User Warnings
People with known hypersensitivity to (fluoro)quinolones should avoid contact with the veterinary medicinal product.
Avoid skin and eye contact.
Rinse any splashes from skin or eyes immediately with water.
Wash hands and exposed skin after use.
Do not eat, drink or smoke 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), if necessary
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 mixes with other veterinary medicinal product.

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 250 ml; 6 x 250 ml
Not all pack sizes may be marketed.
To be supplied only on veterinary prescription.
MA-No.: 24745/4020

Approved: 24 July 2018