PARTICULARS TO APPEAR ON THE OUTER PACKAGE {Box}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Enrotron 5 mg/ml oral solution

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:

Active substance:
Enrofloxacin 5.0 mg

3. PACKAGE SIZE

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

4. TARGET SPECIES

Pigs (piglet)

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Oral use.

7. WITHDRAWAL PERIODS

Withdrawal periods:
Meat and offal: 7 days

8. EXPIRY DATE

Exp. {mm/yyyy}
Once opened, use by…
Once opened, use within 3 months.

9. SPECIAL STORAGE PRECAUTIONS

Keep the bottle tightly closed.

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

aniMedica GmbH

14. MARKETING AUTHORISATION NUMBERS

Vm 24745/4020

15. BATCH NUMBER

Lot {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

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:
Active substance:
Enrofloxacin 5.0 mg

3. TARGET SPECIES

Pigs (piglets)

4. ROUTES OF ADMINISTRATION

Oral use.
Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Withdrawal periods:
Meat and offal: 7 days

6. EXPIRY DATE

Exp. {mm/yyyy}
Once opened, use by…
Once opened, use within 3 months.

7. SPECIAL STORAGE PRECAUTIONS

Keep the bottle tightly closed.

8. NAME OF THE MARKETING AUTHORISATION HOLDER

aniMedica GmbH

9. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Enrotron 5 mg/ml oral solution for pigs

2. Composition

Each ml contains:

Active substance:
Enrofloxacin 5.0 mg

Excipients:
Benzyl alcohol (E-1519) 14.0 mg

Clear slightly yellow solution.

3. Target species

Pigs (piglet)

4. Indications for use

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.

Do not use in cases of confirmed or suspected resistance to quinolones, since a high degree of cross resistance between enrofloxacin and other quinolones does exist.

6. Special warnings

Special precautions for safe use in the target species:
Use of the product should be in accordance with official, national and regional antimicrobial policies.
The use of 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.
Whenever possible, fluoroquinolones should be used based on susceptibility testing.
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.
Not for use for prophylaxis.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
People with known hypersensitivity to (fluoro)quinolones, such as Enrofloxacin, 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 veterinary medicinal product is administered together with substances containing magnesium or aluminium.
Do not combine enrofloxacin with steroidal anti-inflammatory veterinary medicinal products.

Overdose:
Do not exceed the recommended treatment dose. In accidental overdose there is no antidote and treatment should be symptomatic.

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

7. Adverse events

None known.

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 its local representative using the contact details at the end of

this leaflet, or via your national reporting system at https://www.gov.uk/report-veterinary-medicine-problem.

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

Oral use.

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.

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 periods

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 after Exp.
The expiry date refers to the last day of that month.

12. Special precautions for disposal

Medicines should not be disposed of via wastewater.
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

Vm 24745/4020

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.

15. PID link (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

16. Contact details

Marketing authorisation holder:

aniMedica GmbH
Im Südfeld 9
48308 Senden-Bösensell
Germany

Manufacturer responsible for batch release:
aniMedica GmbH
Im Südfeld 9
48308 Senden-Bösensell
Germany

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

Local representatives and contact details to report suspected adverse reactions:
FORTE Healthcare Limited
Block 3, Unit 9
CityNorth Business Campus
Stamullen, Co.
Meath. K32 D990
Republic of Ireland
Tel.: +353 1 841 7666

17. Other information

POM-V

Gavin Hall
Approved: 11 September 2026