

<PARTICULARS TO APPEAR ON THE OUTER PACKAGE>

{Cardboard box}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Enrotron 100 mg/ml solution for use in drinking water for chickens, turkeys and rabbits
Enrofloxacin

2. STATEMENT OF ACTIVE SUBSTANCES

1 ml contains:

Active substance:

Enrofloxacin 100.0 mg

3. PHARMACEUTICAL FORM

Solution for use in drinking water

4. PACKAGE SIZES

100 ml

12 x 100 ml

6 x 1000 ml

5. TARGET SPECIES

Chickens, turkeys, rabbits

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Oral use via the drinking water.
Medicated drinking water should be replaced every 24 hours.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal periods:

Chickens:

Meat and offal: 7 days

Turkeys:

Meat and offal: 13 days

Rabbits:

Meat and offal: 15 days

Not authorised for use in birds producing eggs for human consumption.
Do not administer to layer replacement birds within 14 days of coming into lay.

9. SPECIAL WARNING(S), IF NECESSARY

For special user warnings, 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 according to directions: 24 hours.

11. SPECIAL STORAGE CONDITIONS

Keep the container 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: please read the 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.

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
Germany

Distributor

Forte Healthcare Ltd
Cougar Lane
Naul
Co. Dublin
Ireland

16. MARKETING AUTHORISATION NUMBER

Vm 24745/4022

17. MANUFACTURER'S BATCH NUMBER

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

<PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE>

{Bottle 100 ml}

The 1000 ml bottle will be presented with a combined label (for which the detailed text is provided separately at the end of this document).

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Enrotron 100 mg/ml solution for use in drinking water for chickens, turkeys and rabbits
Enrofloxacin

2. STATEMENT OF ACTIVE SUBSTANCES

1 ml contains:

Active substance:

Enrofloxacin 100.0 mg

3. PHARMACEUTICAL FORM

Solution for use in drinking water.

4. PACKAGE SIZES

100 ml

5. TARGET SPECIES

Chickens, turkeys, rabbits

6. INDICATION(S)

.]

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Oral use via the drinking water.
Medicated drinking water should be replaced every 24 hours.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal periods:
Chickens:
Meat and offal: 7 days
Turkeys:
Meat and offal: 13 days

Rabbits:
Meat and offal: 15 days

Not authorised for use in birds producing eggs for human consumption.
Do not administer to layer replacement birds within 14 days of coming into lay.

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 according to directions: 24 hours.

11. SPECIAL STORAGE CONDITIONS

Keep the container 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

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16. MARKETING AUTHORISATION NUMBER

Vm 24745/4022

17. MANUFACTURER'S BATCH NUMBER

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

PACKAGE LEAFLET

Enrotron 100 mg/ml solution for use in drinking water for chickens, turkeys and rabbits

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 100 mg/ml solution for use in drinking water for chickens, turkeys and rabbits
Enrofloxacin

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

1 ml contains:

Active substance:

Enrofloxacin 100.0 mg

Excipients:

Benzyl alcohol (E-1519) 14.0 mg

Clear, yellowish solution

4. INDICATION(S)

Treatment of infections caused by the following bacteria susceptible to enrofloxacin:

Chickens

Mycoplasma gallisepticum,
Mycoplasma synoviae,
Avibacterium paragallinarum,
Pasteurella multocida.

Turkeys

Mycoplasma gallisepticum,
Mycoplasma synoviae,
Pasteurella multocida.

Rabbits

For the treatment of infectious diseases due to *Pasteurella multocida* and bacterial enteritis due to infection with *E. coli*.

Enrofloxacin should be used where clinical experience, supported where possible by sensitivity testing of the causal organism, indicates enrofloxacin as the active substance of choice.

5. CONTRAINDICATIONS

Do not use when resistance / cross resistance to (fluoro)quinolones is known to occur in the flock intended for treatment.

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

Do not use for prophylaxis.

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

Chickens, turkeys, rabbits

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

Chickens and turkeys

10 mg enrofloxacin/kg bodyweight per day for 3–5 consecutive days.

Treatment for 3–5 consecutive days; for 5 consecutive days in mixed infections and chronic progressive forms. If no clinical improvement is achieved within 2–3 days, alternative antimicrobial therapy should be considered based on susceptibility testing.

Via the drinking water. Always make sure that the entire dose offered has been consumed. The medicated water should be made up fresh each day just before it is offered to the animals. The drinking water must be medicated throughout the treatment period, and no other water source should be available. Determine the bodyweight of the birds as accurately as possible in order to avoid underdosing.

Use only fresh pre-solutions, prepared every day before start of treatment. Pumping systems should be checked constantly to assure proper medication. Empty the water system and fill it with medicated water before starting the treatment.

Calculate the daily quantity (ml) of Enrotron 100 mg/ml required for treatment period as follows:

Total number of birds x Average body weight in kg x 0.1 = Total volume (ml) per day
Enrotron 100 mg/ml may be put directly into the header tank or introduced via a water proportioner pump.

Rabbits

10 mg/kg bodyweight per day for 5 consecutive days.

Calculate the daily quantity (ml) of Enrotron 100 mg/ml required for treatment period as follows:

Total number of rabbits x Average body weight in kg x 0.1 = Total volume (ml) per day

Medicated drinking water should be replaced every 24 hours.

9. ADVICE ON CORRECT ADMINISTRATION

Please refer to section 8.

10. WITHDRAWAL PERIOD

Chickens:

Meat and offal: 7 days

Turkeys:

Meat and offal: 13 days

Rabbits:

Meat and offal: 15 days

Not authorised for use in birds producing eggs for human consumption.

Do not administer to layer replacement birds within 14 days of coming into lay.

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 precautions for each target species

Treatment of *Mycoplasma* spp. infections may not eradicate the organism.

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.

Since enrofloxacin was first authorised for use in poultry, there has been widespread reduction in susceptibility of *E. coli* to fluoroquinolones and emergence of resistant organisms. Resistance has also been reported in *Mycoplasma synoviae* in the EU.

Whenever possible fluoroquinolones should only be used based on susceptibility testing.

Use of the veterinary medicinal product deviating from the instructions given may increase the prevalence of bacteria resistant to the fluoroquinolones and may decrease the effectiveness of treatment with other fluoroquinolones due to the potential for cross-resistance.

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 eat, drink or smoke whilst using the product.

Interaction with other medicinal products and other forms of interaction

In vitro, an antagonism was shown, when combining fluoroquinolones with bacteriostatic antimicrobial agents such as macrolides or tetracyclines and phenicols. The simultaneous application of substances containing aluminium or magnesium can impair the absorption of enrofloxacin.

Overdose

No adverse clinical symptoms were observed in chickens and turkeys treated respectively with doses up to 10 and 6 times higher than the therapy dose. Use of fluoroquinolones during the growth phase combined with a marked and prolonged increase in the intake of drinking water, and hence active ingredient, possibly due to high temperatures, may potentially be associated with damage of the articular cartilage.

Incompatibilities

In absence of compatibility studies, this veterinary medicinal product must not be mixed 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.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

{DD/MM/YYYY}

15. OTHER INFORMATION

Package size: 100 ml, 12 x 100 ml, 1000 ml, 6 x 1000 ml, each with a pitcher
Not all pack sizes may be marketed.
To be supplied only on veterinary prescription.
MA-No.: XXXXXX

Combined Label

Enrotron 100 mg/ml solution for use in drinking water for chicken, turkeys and rabbits

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
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48308 Senden-Bösensell
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2. NAME OF THE VETERINARY MEDICINAL PRODUCT

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Enrofloxacin

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

1 ml contains:

Active substance:

Enrofloxacin 100.0 mg

Excipients:

Benzyl alcohol (E-1519) 14.0 mg

4. PHARMACEUTICAL FORM

Solution for use in drinking water.
Clear yellowish solution

5. PACKAGE SIZE

Pack size:

1000 ml

6. INDICATION(S)

Treatment of infections caused by the following bacteria susceptible to enrofloxacin:

Chickens

Mycoplasma gallisepticum,
Mycoplasma synoviae,
Avibacterium paragallinarum,
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Do not use in case of known hypersensitivity to the active substance, other (fluoro)quinolones or to any of the excipients.

Do not use for prophylaxis.

8. 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}.

9. TARGET SPECIES

Chickens, turkeys, rabbits

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

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Calculate the daily quantity (ml) of Enrotron 100 mg/ml required for treatment period as follows:

Total number of birds x Average body weight in kg x 0.1 = Total volume (ml) per day

Enrotron 100 mg/ml may be put directly into the header tank or introduced via a water proportioner pump.

Rabbits

10 mg/kg bodyweight per day for 5 consecutive days.

Calculate the daily quantity (ml) of Enrotron 100 mg/ml required for treatment period as follows:

Total number of rabbits x Average body weight in kg x 0.1 = Total volume (ml) per day

Medicated drinking water should be replaced every 24 hours.

11. ADVICE ON CORRECT ADMINISTRATION

Please refer to section 8.

12. WITHDRAWAL PERIOD(S)

Withdrawal periods:

Chickens:

Meat and offal: 7 days

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Meat and offal: 13 days

Rabbits:

Meat and offal: 15 days.

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Do not administer to layer replacement birds within 14 days of coming into lay.

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Incompatibilities

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

15. 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.

16. DATE ON WHICH THE LABEL WAS LAST APPROVED

{DD/MM/YYYY}

17. OTHER INFORMATION

Pack sizes:

100 ml, 12 x 100 ml, 1000 ml, 6 x 1000 ml, each with a pitcher

Not all pack sizes may be marketed.

18. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

Restrictions regarding supply and use:

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

Vm 24745/4022

22. MANUFACTURER'S BATCH NUMBER

Manufacturer's batch number:

<Batch>

Approved: 13 July 2018

