

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Box with one 100ml vial

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ENROSYVA 100 mg/ml solution for injection for cattle and pigs.

Enrofloxacin

2. STATEMENT OF ACTIVE SUBSTANCES

Enrofloxacin 100 mg/ml

3. PHARMACEUTICAL FORM

Solution for injection.

4. PACKAGE SIZE

100ml

5. TARGET SPECIES

Cattle and pigs.

6. INDICATION(S)**7. METHOD AND ROUTE(S) OF ADMINISTRATION**

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Withdrawal periods:

Cattle:

Following intravenous injection:

Meat and offal: 5 days.

Milk: 3 days.

Following subcutaneous injection:

Meat and offal: 12 days.

Milk: 4 days.

Pigs:

Meat and offal: 13 days.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}

Once opened, use within 28 days.

11. SPECIAL STORAGE CONDITIONS

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY
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Dispose of waste material in accordance with local requirements.

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”
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Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Laboratorios SYVA S.A.U.
Avda. Párroco Pablo Díez,
49-57 (24010) León
Spain

16. MARKETING AUTHORISATION NUMBER(S)
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17. MANUFACTURER'S BATCH NUMBER
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Batch {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE>

100ml glass vial label

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ENROSYVA 100 mg/ml solution for injection for cattle and pigs.

Enrofloxacin

2. STATEMENT OF ACTIVE SUBSTANCES

Enrofloxacin 100 mg/ml

3. PHARMACEUTICAL FORM

Solution for injection.

4. PACKAGE SIZE

100ml

5. TARGET SPECIES

Cattle and pigs.

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Withdrawal periods:

Cattle:

Following intravenous injection:

Meat and offal: 5 days.

Milk: 3 days.

Following subcutaneous injection:

Meat and offal: 12 days.

Milk: 4 days.

Pigs:

Meat and offal: 13 days.

9. SPECIAL WARNING(S), IF NECESSARY

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10. EXPIRY DATE

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Laboratorios SYVA S.A.U.
Avda. Párroco Pablo Díez,
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Spain

16. MARKETING AUTHORISATION NUMBER(S)
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17. MANUFACTURER’S BATCH NUMBER
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Batch {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE - COMBINED LABEL AND PACKAGE LEAFLET

250 ml polypropylene vial

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:

Laboratorios SYVA S.A.U.
Avda. Párroco Pablo Díez,
49-57 (24010) León
Spain

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

ENROSYVA 100 mg/ml solution for injection for cattle and pigs.

Enrofloxacin

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

Each ml contains:

Active substance:

Enrofloxacin 100 mg

Excipients:

Benzyl alcohol (E 1519)..... 10 mg

Clear, yellow solution, free from visible particles.

4. PHARMACEUTICAL FORM

Solution for injection

5. PACKAGE SIZE

250ml

6. INDICATION(S)

Cattle:

Treatment of infections of the respiratory tract caused by enrofloxacin susceptible strains of *Pasteurella multocida*, *Mannheimia haemolytica* and *Mycoplasma* spp.

Treatment of acute severe mastitis caused by enrofloxacin susceptible strains of *Escherichia coli*.

Treatment of infections of the alimentary tract caused by enrofloxacin susceptible strains of *Escherichia coli*.

Treatment of septicaemia caused by enrofloxacin susceptible strains of *Escherichia coli*.

Treatment of acute mycoplasma-associated arthritis due to enrofloxacin susceptible strains of *Mycoplasma bovis* in cattle less than 2 years old.

Pigs:

Treatment of infections of the respiratory tract caused by enrofloxacin susceptible strains of *Pasteurella multocida*, *Mycoplasma* spp. and *Actinobacillus pleuropneumoniae*.

Treatment of infections of the urinary tract caused by enrofloxacin susceptible strains of *Escherichia coli*.

Treatment of post-partum dysgalactiae syndrome, PDS (MMA syndrome) caused by enrofloxacin susceptible strains of *Escherichia coli* and *Klebsiella* spp.

Treatment of infections of the alimentary tract caused by enrofloxacin susceptible strains of *Escherichia coli*.

Treatment of septicaemia caused by enrofloxacin susceptible strains of *Escherichia coli*.

7. CONTRAINDICATIONS

Do not use in the case of hypersensitivity to fluoroquinolones or to any of the excipients.

Do not use in growing horses because of possible deleterious damage on articular cartilage.

8. ADVERSE REACTIONS

In pigs, inflammatory reactions after intramuscular administration may occur commonly.

In cattle, inflammatory reaction of variable intensity and persistence at the administration point could be observed rarely after subcutaneously administration.

Digestive tract disorders (anorexia, vomiting and diarrhoea) may occur very rarely. These signs are generally mild and transient.

In cattle, shock reactions could be observed very rarely after intravenous administration, presumably as a result of circulatory impairment.

The frequency of adverse reactions is defined using the following convention:

- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)

- very rare (less than 1 animal in 10,000 animals treated, including isolated reports)

If you notice any side, even those not already listed in this label or you think that the medicine has not worked, please inform your veterinary surgeon.

Alternatively, you can report via your national reporting system.

9. TARGET SPECIES

Cattle and pigs.

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

Intravenous, subcutaneous or intramuscular use.

Repeated injections should be made at different injection sites.

Cattle:

5 mg of enrofloxacin/kg bw, corresponding to 1 ml/20 kg bw, once daily for 3-5 days.

Acute mycoplasma-associated arthritis due to enrofloxacin susceptible strains of *Mycoplasma bovis* in cattle less than 2 years old: 5 mg of enrofloxacin/kg bw, corresponding to 1 ml/20 kg bw, once daily for 5 days.

The product can be administered by slow intravenous or subcutaneous administration.

Acute mastitis caused by *Escherichia coli*: 5 mg enrofloxacin/kg bw, corresponding to 1 ml/20 kg bw, by slow intravenous injection once daily for two consecutive days.

The second dose may be administered by the subcutaneous route. In this case, the withdrawal period following subcutaneous injection applies.

Not more than 10 ml should be administered at one subcutaneous injection site.

Pigs:

2.5 mg of enrofloxacin/kg bw, corresponding to 0.5 ml/20 kg bw, once daily by intramuscular injection for 3 days.

Alimentary tract infection or septicaemia caused by *Escherichia coli*: 5 mg of enrofloxacin/kg bw, corresponding to 1 ml/20 kg bw, once daily by intramuscular injection for 3 days.

In pigs, the injection should be made in the neck at the ear base.

Not more than 3 ml should be administered at one intramuscular injection site.

11. ADVICE ON CORRECT ADMINISTRATION

To ensure a correct dosage, body weight (bw) should be determined as accurately as possible to avoid underdosing.

12. WITHDRAWAL PERIOD(S)

Withdrawal periods:

Cattle:

Following intravenous injection:

Meat and offal: 5 days.

Milk: 3 days.

Following subcutaneous injection:

Meat and offal: 12 days.

Milk: 4 days.

Pigs:

Meat and offal: 13 days.

13. SPECIAL STORAGE PRECAUTIONS

This veterinary medicinal product does not require any special storage conditions.

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.

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.

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

Use of the product including use deviating from instructions given in the SPC may increase the prevalence of bacteria resistant to the enrofloxacin and may decrease the effectiveness of treatment with other fluoroquinolones due to the potential for cross resistance.

Degenerative changes of articular cartilage were observed in calves treated orally with 30 mg enrofloxacin/kg bw during 14 days.

The use of enrofloxacin in growing lambs at the recommended dose for 15 days caused histological changes in the articular cartilage, not associated to clinical signs.

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

People with known hypersensitivity to fluoroquinolones should avoid contact with the veterinary medicinal product.

Care should be taken to avoid accidental self-injection. In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

The product is an alkaline solution. Avoid contact with skin or eyes. Wash any splashes from skin or eyes immediately with water.

Wash hands after use.

Do not eat, drink or smoke while handling the product.

Pregnancy:

The safety of the veterinary medicinal product has not been established during pregnancy. Use only accordingly to the benefit/risk assessment by the responsible veterinarian.

Interaction with other medicinal products and other forms of interaction:

Do not use enrofloxacin concomitantly with antimicrobial substances acting antagonistically to quinolones (e.g. macrolides, tetracyclines or phenicols).

Do not use concurrently with theophylline as the elimination of theophylline may be delayed.

Overdose (symptoms, emergency procedures, antidotes):

In cases of accidental overdoses digestive tract disorders (e.g. vomiting, diarrhoea) and neurological disorders may occur.

In accidental overdose there is no antidote and treatment should be symptomatic.

Incompatibilities:

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

Do not mix with acid products that may precipitate the enrofloxacin.

15. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY
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Medicines should not be disposed of via wastewater or household waste.

Ask your veterinary or pharmacist 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
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17. OTHER INFORMATION

Pack sizes:

Box with 1 glass vial of 100ml.

Polypropylene vial of 250ml.

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

To be administered exclusively by a veterinarian (in the case of intravenous administration).

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 within 28 days.

Shelf life after first opening the container: 28 days.

21. MARKETING AUTHORISATION NUMBER(S)
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22. MANUFACTURER’S BATCH NUMBER
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Batch {number}