[Version 9,03/2022] corr. 11/2022

ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:

Enrofloxacin .....100 mg

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Benzyl alcohol (E 1519)	10 mg
Potassium hydroxide	
Water for injections	

Clear, yellow solution, free from visible particles.

3. CLINICAL INFORMATION

3.1 Target species

Cattle and pigs.

3.2 Indications for use for each target species

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*.

3.3 Contraindications

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

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

3.4 Special warnings

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.

3.5 Special precautions for use

Special precautions for safe use in the target species:

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.

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 and benzyl alcohol 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 veterinary medicinal 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.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Pigs:

Common: (1 to 10 animals / 100 animals treated):	Injection site inflammation[1].

[1] After intramuscular administration.

Cattle:

Rare (1 to 10 animals / 10,000 animals treated):	Injection site inflammation[1]
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Digestive tract disorders (anorexia, vomiting and diarrhoea) [2] Circulatory shock[3]

[1] Variable intensity and persistence. Observed after subcutaneously administration
[2]These signs are generally mild and transient.

[3] After intravenous administration, presumably as a result of circulatory impairment.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder <or its local representative> or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

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

3.8 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.

3.9 Administration routes and dosage

Intravenous, subcutaneous or intramuscular use.

Repeated injections should be made at different injection sites.

To ensure a correct dosage, body weightshould be determined as accurately as possible.

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.

3.10 Symptoms of overdose (and where applicable, emergency procedures and 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.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

<To be completed nationally>

3.12 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.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QJ01MA90

4.2 Pharmacodynamics

Mode of action

Two enzymes essential in DNA replication and transcription, DNA gyrase and topoisomerase IV, have been identified as the molecular targets of fluoroquinolones. Target inhibition is caused by non-covalent binding of fluoroquinolone molecules to these enzymes. Replication forks and translational complexes cannot proceed beyond such enzyme-DNA-fluoroquinolone complexes, and inhibition of DNA and mRNA synthesis triggers events resulting in a rapid, drug concentration-dependent killing of pathogenic bacteria. The mode of action of enrofloxacin is bactericidal and bactericidal activity is concentration dependent.

Antibacterial spectrum

Enrofloxacin is active against many Gram-negative bacteria such as *Escherichia coli, Klebsiella spp., Actinobacillus pleuropneumoniae, Mannheimia haemolytica, Pasteurella spp*. (e.g. *Pasteurella multocida*), against Gram-positive bacteria such as *Staphylococcus spp*. (e.g. *Staphylococcus aureus*) and against *Mycoplasma spp*. at the recommended therapeutic doses.

Types and mechanisms of resistance

Resistance to fluoroquinolones has been reported to arise from five sources, (i) point mutations in the genes encoding for DNA gyrase and/or topoisomerase IV leading to alterations of the respective enzyme, (ii) alterations of drug permeability in Gram-negative bacteria, (iii) efflux mechanisms, (iv) plasmid mediated resistance and (v) gyrase protecting proteins. All mechanisms lead to a reduced susceptibility of the bacteria to fluoroquinolones. Cross-resistance within the fluoroquinolone class of antimicrobials is common.

4.3 Pharmacokinetics

Enrofloxacin is rapidly absorbed after parenteral injection. Bioavailability is high (approximately 100% in pig and cattle) with a low to moderate plasma protein binding (approximately 20 to 50%). Enrofloxacin is metabolized to the active substance ciprofloxacin at approximately 40% in dogs and ruminants and less than 10% in pigs and cats.

Enrofloxacin and ciprofloxacin distribute well into all target tissues, e.g. lung, kidney, skin and liver, reaching 2- to 3-fold higher concentrations than in plasma. Parent substance and active metabolite are cleared from the body via urine and faeces.

Accumulation in plasma does not occur following a treatment interval of 24 h.

CATTLE:

After an intramuscular dose of 5 mg enrofloxacin per kg body weight (bw) to cattle, maximum concentration of 1µg/ml is observed and it is maintained for more than 6 hours. Distribution volume is equal to 0.6 l/kg, plasma elimination half-life is 2h and the body clearance is 210 ml/kg/h.

In cows, plasma elimination half-life was about 3h.

After i.v. administration of 2.5mg/kg to cows, enrofloxacin and ciprofloxacin in milk could be observed after 15 minutes. In dairy cattle, after intravenous administration, peak concentrations in milk are reached after 0.7 to 1.3 hours, while maximum concentrations of the active metabolite ciprofloxacin are reached after 5-8 hours from the administration. Concentrations of enrofloxacin in milk are similar to those in plasma.

PIGS

After i.v. administration of a dose of 5mg/kg of enrofloxacin, a wide volume of distribution of 3.9 l/kg was observed. After an i.v. administration of 2.5 mg/kg, plasma elimination half-life was 9.6h and the mean residence time was 12.8h.

After i.m. administration of 2.5 mg/ kg, the plasma elimination half-life was 12.1 h, the mean residence time was 17.2 h and the maximum concentration was 1.2 µg / ml.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

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

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.

Shelf life after first opening the immediate packaging: 28 days.

5.3 Special precautions for storage

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

5.4 Nature and composition of immediate packaging

Type II coloured glass vials sealed with bromobutyl stoppers and aluminium cap.
Polypropylene vials sealed with bromobutyl stoppers and aluminium cap.

Pack Sizes:
Cardboard box with 1 glass vial of 100 ml.

Polypropylene vial of 250 ml.

Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater <or household waste>.

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 national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Laboratorios Syva S.A.

7. MARKETING AUTHORISATION NUMBER(S)

8. DATE OF FIRST AUTHORISATION

Date of first authorisation:> <{DD/MM/YYYY}><{DD month YYYY}.>

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

<{MM/YYYY}>

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

ANNEX III

LABELLING AND PACKAGE LEAFLET

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

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:

Enrofloxacin .....100 mg

3. PACKAGE SIZE

100 ml

4. TARGET SPECIES

Cattle and pigs.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Intravenous, subcutaneous or intramuscular use.

7. WITHDRAWAL PERIODS

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.

8. EXPIRY DATE

Exp. {mm/yyyy}

Once broached use by:…
Shelf life after first opening the container: 28 days

9. SPECIAL STORAGE PRECAUTIONS

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

Laboratorios Syva S.A.

14. MARKETING AUTHORISATION NUMBERS

15. BATCH NUMBER

Lot {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

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:

Enrofloxacin .....100 mg

3. TARGET SPECIES

Cattle and pigs.

4. ROUTES OF ADMINISTRATION

Intravenous, subcutaneous or intramuscular use.

5. WITHDRAWAL PERIODS

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.

6. EXPIRY DATE

Exp. {mm/yyyy}
Once broached use by:…
Shelf life after first opening the container: 28 days

7. SPECIAL STORAGE PRECAUTIONS

8. NAME OF THE MARKETING AUTHORISATION HOLDER

Laboratorios Syva S.A.

9. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE - <u>COMBINED LABEL AND PACKAGE LEAFLET</u>

250 ml polypropylene vial

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. COMPOSITION

Each ml contains:

Active substance:

Enrofloxacin .....100 mg

Excipients:

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

Clear, yellow solution, free from visible particles.

3. PACKAGE SIZE

250 ml

4. TARGET SPECIES

Cattle and pigs.

5. INDICATIONS FOR USE

<u>Cattle:</u>

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.

<u>Pigs:</u>

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*.

6. CONTRAINDICATIONS

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

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

7. SPECIAL WARNINGS

Special warnings:

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.

Special precautions for safe use in the target species:

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.

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 and benzyl alcohol 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 veterinary medicinal 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.

Interactions 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:

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.

Special restrictions for use and special conditions for use

<To be completed nationally>

Major 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.

8. ADVERSE EVENTS

Adverse events

Pigs:

Common: (1 to 10 animals / 100 animals treated):	Injection site inflammation[1].

[1] After intramuscular administration.

Cattle:

Rare (1 to 10 animals / 10,000 animals treated):	Injection site inflammation[1]
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Digestive tract disorders (anorexia, vomiting and diarrhoea) [2] Circulatory shock[3]

[1] Variable intensity and persistence. Observed after subcutaneously administration
[2]These signs are generally mild and transient.

[3] After intravenous administration, presumably as a result of circulatory impairment.

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed on this label, 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><the local representative of the marketing authorisation holder> using the contact details on this label, or via your national reporting system {national system details}.>

9. DOSAGE FOR EACH TARGET SPECIES, ROUTES 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.

10. ADVICE ON CORRECT ADMINISTRATION

To ensure a correct dosage, body weight should be determined as accurately as possible.

11. WITHDRAWAL PERIODS

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.

12. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

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.

13. SPECIAL PRECAUTIONS FOR DISPOSAL

Special precautions for disposal

Medicines should not be disposed of via wastewater or household waste.

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.

14. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription

15. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Pack sizes

Box with 1 glass vial of 100 ml.

Polypropylene vial of 250 ml.

Not all pack sizes may be marketed

16. DATE ON WHICH THE LABEL WAS LAST REVISED

Date on which the label was last revised

<{MM/YYYY}>

Detailed information on this veterinary medicinal product is available in the Union Product Database.

17. CONTACT DETAILS

Contact details

Marketing authorisation holder:

Laboratorios Syva S.A.
Calle Marqués de la Ensenada, 16
28004 MADRID
ESPAÑA

Manufacturer responsible for batch release:

Laboratorios Syva S.A.
Avenida del Párroco Pablo Díez, 49-57
San Andrés del Rabanedo
24010 LEÓN
ESPAÑA

Local representatives and contact details to report suspected adverse reactions:

<For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder listed below.>

Ελλάδα
Local representative:
Premier Shukuroglou Hellas S.A.
Τηλ: +30 210 6538061
e-mail: psh@premier.com.gr
Contact details to report suspected adverse reactions:
Premier Shukuroglou Hellas S.A.
Τηλ: +30 6947619393
e-mail: pvreport@premier.com.gr

España
Contact details to report suspected adverse reactions:
Laboratorios Syva S.A.
Parque Tecnológico de León
C/ Nicostrato Vela M15-M16
24009 LEÓN
ESPAÑA
Tel: + 34 987 800 800
E-mail: farmacovigilancia@syva.es

Italia
Local representative:
IZO s.r.l. a socio unico
Via San Zeno 99/A
25124 Brescia - Italia
Tel: + 39 030 2420583
Contact details to report suspected adverse reactions:
Laboratorios Syva S.A.
Parque Tecnológico de León
C/ Nicostrato Vela M15-M16
24009 LEÓN
ESPAÑA
Tel: + 34 987 800 800
E-mail: farmacovigilancia@syva.es

Portugal
Contact details to report suspected adverse reactions:
Laboratorios Syva S.A.
Parque Tecnológico de León
C/ Nicostrato Vela M15-M16
24009 LEÓN
Tel: + 351 219 747 934
E-mail: syva.portugal@syva.pt

Polska
Local representative:
Grabikowski-Grabikowska Przedsiębiorstwo Produkcyjno-Handlowo-Usługowe "INEX" Sp. j.ul. Białostocka 12, 11-500 Giżycko, Polska
Tel.: + 48 87 429 17 19
Contact details to report suspected adverse reactions:
Grabikowski-Grabikowska Przedsiębiorstwo Produkcyjno-Handlowo-Usługowe "INEX" Sp. j.
Tel.: +48 795 128 650
e-mail: bezpieczenstwo@inexwet.pl

18. OTHER INFORMATION

19. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

20. EXPIRY DATE

Exp. {mm/yyyy}

Once opened, use by:…

Shelf life after first opening the container: 28 days.

21. BATCH NUMBER

Lot {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

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

2. Composition

Each ml contains:

Active substance:

Enrofloxacin .....100 mg

Excipients:

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

Clear, yellow solution, free from visible particles.

3. Target species

Cattle and pigs.

4. Indications for use

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*.

5. Contraindications

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

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

6. Special warnings

Special warnings:

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.

Special precautions for safe use in the target species:

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.

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 and benzyl alcohol 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 veterinary medicinal 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:

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.

Special restrictions for use and special conditions for use

<To be completed nationally>

Major 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.

7. Adverse events

Pigs

Common: (1 to 10 animals / 100 animals treated):	Inflammatory reactions / Injection site inflammation[1].

[1] After intramuscular administration.

Cattle

Rare (1 to 10 animals / 10,000 animals treated):	Inflammatory reaction at the administration point / Injection site inflammation[1]
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Digestive tract disorders (anorexia, vomiting and diarrhoea)[2] Shock reactions / Circulatory shock[3]

[1] Variable intensity and persistence. Observed after subcutaneously administration
[2]These signs are generally mild and transient.

[3] After intravenous administration, presumably as a result of circulatory impairment.

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 the local representative of the marketing authorisation holder> using the contact details at the end of this leaflet, or via your national reporting system: <{national system details}*[listed in Appendix I*]*>.

*[*For the printed material, please refer to the guidance of the annotated QRD template.]*

8. Dosage for each species, routes 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.

9. Advice on correct administration

To ensure a correct dosage, body weight should be determined as accurately as possible.

10. 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.

11. Special storage precautions

Keep out of the sight and reach of children.

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

Shelf life after first opening the container: 28 days.

12. Special precautions for disposal

Medicines should not be disposed of via wastewater or household waste.

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

Pack sizes:
Box with 1 glass vial of 100ml.
Polypropylene vial of 250ml.

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

<{MM/YYYY}>

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

16. Contact details

Marketing authorisation holder <and manufacturer responsible for batch release> <and contact details to report suspected adverse reactions>:

Laboratorios SYVA S.A.
Calle Marqués de la Ensenada, 16
28004 MADRID
ESPAÑA

Manufacturer responsible for batch release:

Laboratorios Syva S.A.
Avenida del Párroco Pablo Díez, 49-57
San Andrés del Rabanedo
24010 LEÓN
ESPAÑA

Local representatives <and contact details to report suspected adverse reactions>:

<For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.>

Ελλάδα
Local representative:
Premier Shukuroglou Hellas S.A.
Τηλ: +30 210 6538061
e-mail: psh@premier.com.gr
Contact details to report suspected adverse reactions:
Premier Shukuroglou Hellas S.A.
Τηλ: +30 6947619393
e-mail: pvreport@premier.com.gr

España
Contact details to report suspected adverse reactions:
Laboratorios Syva S.A.
Parque Tecnológico de León
C/ Nicostrato Vela M15-M16
24009 LEÓN
ESPAÑA
Tel: + 34 987 800 800
E-mail: farmacovigilancia@syva.es

Italia
Local representative:
IZO s.r.l. a socio unico
Via San Zeno 99/A
25124 Brescia - Italia
Tel: + 39 030 2420583
Contact details to report suspected adverse reactions:
Laboratorios Syva S.A.
Parque Tecnológico de León
C/ Nicostrato Vela M15-M16
24009 LEÓN
ESPAÑA
Tel: + 34 987 800 800
E-mail: farmacovigilancia@syva.es

Portugal
Contact details to report suspected adverse reactions:
Laboratorios Syva S.A.
Parque Tecnológico de León
C/ Nicostrato Vela M15-M16
24009 LEÓN
Tel: + 351 219 747 934
E-mail: syva.portugal@syva.pt

Polska
Local representative:
Grabikowski-Grabikowska Przedsiębiorstwo Produkcyjno-Handlowo-Usługowe "INEX" Sp. j.ul. Białostocka 12, 11-500 Giżycko, Polska
Tel.: + 48 87 429 17 19
Contact details to report suspected adverse reactions:
Grabikowski-Grabikowska Przedsiębiorstwo Produkcyjno-Handlowo-Usługowe "INEX" Sp. j.
Tel.: +48 795 128 650
e-mail: bezpieczenstwo@inexwet.pl

17. Other information