PARTICULARS TO APPEAR ON THE INMEDIATE PACKAGE

LABEL ON VIAL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ENRODEXIL 100 mg/ml solution for injection for cattle and pigs
Enrofloxacin

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Active substance:
Enrofloxacin 100.0 mg/ml

Excipients:
Benzyl alcohol (E 1519) 7.8 mg/ml
Disodium edetate 10.0 mg/ml

3. PHARMACEUTICAL FORM

4. PACKAGE SIZE

100 ml
250 ml

5. TARGET SPECIES

Cattle and pigs

6. INDICATION(S)

Read the package leaflet before use.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Subcutaneous or intravenous use in cattle and intramuscular use in pigs.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Withdrawal period
Cattle:
IV: Meat and offal: 5 days
Milk: 3 days
SC: 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: MM/YY
Shelf-life after first opening of the immediate packaging: 28 days.
Once opened, use by:

11. SPECIAL STORAGE CONDITIONS

Protect from light.
Do not freeze.

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

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.

For animal treatment only – to be supplied only on veterinary prescription.
Administration by a veterinary surgeon or under their direct responsibility.

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

INDUSTRIAL VETERINARIA, S.A.
Esmeralda, 19
08950 Esplugues de Llobregat (Barcelona)
SPAIN

16. MARKETING AUTHORISATION NUMBER(S)

Vm 36547/4003

17. MANUFACTURER'S BATCH NUMBER

Batch

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARDBOARD CARTON

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ENRODEXIL 100 mg/ml solution for injection for cattle and pigs
Enrofloxacin

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Active substance:
Enrofloxacin 100.0 mg/ml

Excipients:
Benzyl alcohol (E 1519) 7.8 mg/ml
Disodium edetate 10.0 mg/ml

3. PHARMACEUTICAL FORM

Solution for injection
Clear, slightly yellowish solution

4. PACKAGE SIZE

1 vial of 100 ml
1 vial of 250 ml

5. TARGET SPECIES

Cattle and pigs

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Subcutaneous or intravenous use in cattle and intramuscular use in pigs
Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Withdrawal period
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: MM/YY
Shelf-life after first opening of the immediate packaging: 28 days.
Once opened, use by:

11. SPECIAL STORAGE CONDITIONS

Protect from light.
Do not freeze.

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

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.

For animal treatment only – to be supplied only on veterinary prescription.
Administration by a veterinary surgeon or under their direct responsibility.

14. THE WORDS "KEEP OUT OF SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

INDUSTRIAL VETERINARIA, S.A.
Esmeralda, 19
08950 Esplugues de Llobregat (Barcelona)
SPAIN

16. MARKETING AUTHORISATION NUMBER(S)

Vm 36547/4003

17. MANUFACTURER'S BATCH NUMBER

Batch

PACKAGE LEAFLET

ENRODEXIL 100 mg/ml solution for injection for cattle and 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 and manufacturer responsible for batch release:
INDUSTRIAL VETERINARIA, S.A.
Esmeralda, 19
08950 Esplugues de Llobregat (Barcelona)
SPAIN

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

ENRODEXIL 100 mg/ml solution for injection for cattle and pigs
Enrofloxacin

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

Each 1 ml of solution contains:

Active substance:	
Enrofloxacin	100.0 mg
Excipients	
Benzyl alcohol (E 1519)	7.8 mg
Disodium edetate	10.0 mg

Clear slightly yellowish solution.

4. 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 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*.

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

5. CONTRAINDICATIONS

Do not use for prophylaxis.
Do not use when resistance / cross resistance to (Fluoro)quinolones is known to occur.
Do not use in case of known hypersensitivity to fluoroquinolones or to any of the excipients.
Do not use in growing horses because of possible deleterious damage on articular cartilage.

6. ADVERSE REACTIONS

Local tissue reactions may occasionally occur at the injection site. Normal sterile precautions should be taken.
In cattle, gastrointestinal disturbances may occasionally occur.
If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Cattle and pigs.

8. 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 body weight (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.
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 1.0 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.
The stopper should not be punctured more than 20 times.

9. ADVICE ON CORRECT ADMINISTRATION

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

10. WITHDRAWAL PERIOD

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.
Protect from light.
Do not freeze.
Do not use this veterinary medicinal product after the expiry date which is stated on the carton after "EXP". The expiry date refers to the last day of that month.
Shelf-life after first opening the container: 28 days.
When the container is broached (opened) for the first time, using the in-use shelf-life which is specified on this package insert, the date on which any product remaining in the container should be discarded should be worked out. This discard date should be written in the space provided on the label.

12. SPECIAL WARNING(S)

Special precautions for use in animals
Do not exceed the recommended dose.
Repeat injections should be administered at different sites.
Enrofloxacin should be used with caution in epileptic animals or animals affected by renal dysfunction.
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 with clinical signs.
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 deviating from the instructions given in the SPC may increase the prevalence of bacteria resistant to the fluoroquinolones and may decrease the effectiveness of treatment with other quinolones due to the potential for cross resistance.

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

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

Do not eat, drink or smoke whilst using the product.

Care should be taken to avoid accidental self-injection. If accidental self injection occurs seek medical advice immediately.

Direct contact with the skin should be avoided because of sensitisation, contact dermatitis and possible hypersensitivity reactions. Wear gloves.

Use during pregnancy, lactation or lay

Can be used during pregnancy and lactation.

Interaction with other medicinal products and other forms of interaction

Antagonistic effects due to concurrent administration of macrolides, and tetracyclines may occur Enrofloxacin may interfere with the metabolism of theophylline, decreasing theophylline clearance resulting in increased plasma levels of theophylline.

Overdose (symptoms, emergency procedures, antidotes)

Do not exceed the recommended dose. In accidental overdose (lethargy, anorexia) there is no antidote and treatment should be symptomatic. No signs of over dosage were observed in pigs following administration of the product at five times the recommended therapeutic dose.

Incompatibilities

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

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED VETERINARY MEDICINAL PRODUCT OR WASTE MATERIALS, IF ANY

Any unused veterinary medicinal products or waste material derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

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

Ask your veterinary surgeon or pharmacist 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

15. OTHER INFORMATION

Box with 1 vial of 100 ml.
Box with 1 vial of 250 ml.
Not all pack sizes may be marketed

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

Approved: 18 May 2016