PARTICULARS TO APPEAR ON THE INMEDIATE PACKAGE (LABEL ON VIAL)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each ml contains:

Active substance	
Enrofloxacin	100.0 mg
Excipients	
Benzyl alcohol (E1519)	7.8 mg
Disodium edetate	10.0 mg

3. PHARMACEUTICAL FORM

Solution for injection
Clear, slightly yellowish solution

4. PACKAGE SIZE

100 ml and 250ml

5. TARGET SPECIES

Cattle and pigs

6. INDICATION(S)

Read the package leaflet before use.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Intravenous or subcutaneous use in cattle and intramuscular use in pigs.
Read the package leaflet before use.

8. 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: end 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

Any unused veterinary medicinal products or waste material derived from such veterinary medicinal product should be disposed of 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 REACH AND SIGHT OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

VETPHARMA ANIMAL HEALTH, S.L.
Les Corts, 23
08028 – Barcelona
SPAIN

Distributed by:

16. MARKETING AUTHORISATION NUMBER(S)

17. MANUFACTURER'S BATCH NUMBER

Batch

PARTICULARS TO APPEAR ON THE OUTER PACKAGE (CARDBOARD CARTON)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each ml contains:

Active substance	
Enrofloxacin	100.0 mg
Excipients	
Benzyl alcohol (E1519)	7.8 mg
Disodium edetate	10.0 mg

3. PHARMACEUTICAL FORM

Solution for injection
Clear, slightly yellowish solution

4. PACKAGE SIZE

1 vial of 100 ml
1 vial of 250ml
12 vials of 100 ml
12 vials of 250 ml

5. TARGET SPECIES

Cattle and pigs

6. INDICATION(S)

Read the package leaflet before use.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Intravenous or subcutaneous use in cattle and intramuscular use in pigs.
Read the package leaflet before use.

8. 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: end 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

Any unused veterinary medicinal products or waste material derived from such veterinary medicinal product should be disposed of 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 REACH AND SIGHT OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

VETPHARMA ANIMAL HEALTH, S.L.
Les Corts, 23
08028 – Barcelona
SPAIN

Distributed by:

16. MARKETING AUTHORISATION NUMBER(S)

17. MANUFACTURER'S BATCH NUMBER

Batch

PACKAGE LEAFLET

UNISOL 100 mg/ml solution for injection for cattle and pigs

Enrofloxacin

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder
VETPHARMA ANIMAL HEALTH, S.L.
Les Corts, 23
08028 – Barcelona
SPAIN

Manufacturer for the batch release
INDUSTRIAL VETERINARIA, S.A.
Esmeralda, 19
08950 Esplugues de Llobregat (Barcelona)
SPAIN

CHEMICAL IBÉRICA PV, S.L.
Ctra. Burgos-Portugal, Km. 256,
Calzada de Don Diego, 37448 (Salamanca)
SPAIN

Distributed by

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

UNISOL 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	100.0 mg
Excipients	
Benzyl alcohol (E1519)	7.8 mg
Disodium edetate	10.0 mg

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 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 growing horses because of possible deleterious damage on articular cartilage.

Do not use for prophylaxis.

Do not use when resistance / cross resistance to (Fluoro)quinolones is known to occur.

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

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 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 any 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.
The stopper should not be punctured more than 20 times.

9. ADVICE ON CORRECT ADMINISTRATION

To ensure a correct dosage, body weight (bw) 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 after the expiry date stated on the carton.

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

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

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.

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.

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 and show the package leaflet or the label to the physician.

People with known hypersensitivity to fluoroquinolones should avoid contact with the product. Direct contact with the skin should be avoided because of sensitisation, contact dermatitis and possible hypersensitivity reactions. Wear gloves.

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.

Use during pregnancy, lactation or lay

There is no restriction on the use of this product during pregnancy and lactation.

Interaction with other medicinal products and other forms of interaction

Antagonistic effects due to concurrent administration of bacteriostatic antimicrobial agents such as macrolides or tetracyclines and phenicols may occur.

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.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

Box with 1 vial of 250ml.
Box with 1 vial of 100ml.
Box with 12 vials of 250ml.
Box with 12 vials of 100ml.
Not all the pack sizes may be marketed

Approved: 17 May 2016