ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Box

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AV

CN: XXXXXX

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Colmyc 100 mg/ml solution for injection for cattle, pigs, sheep and goat.

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Enrofloxacin 100 mg/ml

3. PHARMACEUTICAL FORM

Solution for injection
Clear yellow solution

4. PACKAGE SIZE

50 ml, 100 ml and 250 ml

5. TARGET SPECIES

Cattle , sheep, goats and pigs.

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.
Bovine: Subcutaneous/intravenous administration
Sheeps and goats: Subcutaneous administration
Porcine: Intramuscular administration

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.

Sheep:

Meat and offal: 4 days.

Milk: 3 days.

Goats:

Meat and offal: 6 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}>

Shelf-life after first opening the container: Following withdrawal of the first dose, use the product within 28 days. Discard unused material.

PL:Termin ważności (EXP)

11. SPECIAL STORAGE CONDITIONS

This veterinary medicinal product does not require any special storage conditions Protect from light

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

Disposal: read 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.
ES: Exclusive administration by the veterinary surgeon.”

Veterinary medicinal product subject to veterinary prescription that cannot be renewed.

PL: “Wyłącznie dla zwierząt - Wydawany z przepisu lekarza – Rp.

Do podawania pod nadzorem lekarza weterynarii”)

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

SP VETERINARIA SA

Ctra. Reus Vinyols km 4.1

Riudoms (43330)

Tarragona (Spain)

16. MARKETING AUTHORISATION NUMBER(S)

17. MANUFACTURER’S BATCH NUMBER

<Batch> <Lot> <BN> {number}
PL: Nr serii (Lot)

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

vials of 50 ml.

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Colmyc 100 mg/ml solution for injection for cattle, sheep, goats and pigs

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Enrofloxacin 100.0 mg/1 ml

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

Each ml contains:

Active substance:

Enrofloxacin 100.0 mg

Excipients:

n-Butyl alcohol 30 mg

4. ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.
Bovine: Subcutaneous/intravenous administration
Sheeps and goats:: Subcutaneous administration
Porcine: Intramuscular administration

5. 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.

Sheep:

Meat and offal: 4 days.

Milk: 3 days.

Goats:

Meat and offal: 6 days.

Milk: 4 days.

Pigs:

Meat and offal: 13 days.

6. BATCH NUMBER

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

7. EXPIRY DATE

<EXP {month/year}>
Once broached, use before 28 days

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

vials of 100 and 250 ml.

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AV

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Enrofloxacin	100.0 mg
n-Butyl alcohol	30 mg
Other excipients	qt 1 ml

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

100 ml and 250 ml

5. TARGET SPECIES

Cattle, sheep, goats and pigs.

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

IV, SC, IM.

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.

Sheep:

Meat and offal: 4 days.

Milk: 3 days.

Goats:

Meat and offal: 6 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 broached, use before 28 days

11. SPECIAL STORAGE CONDITIONS

This veterinary medicinal product does not require any special storage conditions. Do not freeze. Protect from light

Store in the original package.

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

Disposal: read package leaflet.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

ES: Exclusive administration by the veterinary surgeon.

Veterinary medicinal product subject to veterinary prescription that cannot be renewed.

OTHER CMS :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

SP VETERINARIA SA

Ctra. Reus Vinyols km 4.1

43330 Riudoms

Tarragona (Spain)

16. MARKETING AUTHORISATION NUMBER(S)

EU/0/00/000/000

17. MANUFACTURER'S BATCH NUMBER

B. PACKAGE LEAFLET

PACKAGE LEAFLET
Colmyc 100 mg/ml solution for injection for cattle, pigs , sheep and goat.

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

SP VETERINARIA SA

Ctra. Reus Vinyols km 4.1

43330 Riudoms

Tarragona (Spain)

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Colmyc 100 mg/ml solution for injection for cattle ,pigs, sheep and goat.

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

Enrofloxacin	100.0 mg
n-Butyl alcohol	30 mg
Other excipients	1 ml

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 severe mastitis 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.

Sheep

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 mastitis caused by enrofloxacin susceptible strains of *Staphylococcus aureus* and *Escherichia coli*.

Goats

Treatment of infections of the respiratory tract caused by enrofloxacin susceptible strains of *Pasteurella multocida* and *Mannheimia haemolytica.*
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 mastitis caused by enrofloxacin susceptible strains of *Staphylococcus aureus* and *Escherichia coli*.

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 animals with known hypersensitivity to enrofloxacin or other fluoroquinolones or to any of the excipients.
Do not use in growing horses because of possible deleterious damage on articular cartilage.

6. ADVERSE REACTIONS

Digestive tract disorders (e.g. diarrhoea) may occur in very rare cases. These signs are generally mild and transient.
In very rare cases intravenous treatment of cattle can cause shock reactions, presumably as a result of circulatory impairment.

Local reactions at injection site
In pigs, after intramuscular administration of the product, inflammatory reactions may occur. They may persist up to 28 days after the injection.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals displaying adverse reactions during the course of one treatment)
- common (more than 1 but less than 10 animals in 100 animals)
- uncommon (more than 1 but less than 10 animals in 1,000 animals)

- rare (more than 1 but less than 10 animals in 10,000 animals)
- very rare (less than 1 animal in 10,000 animals, including isolated reports).
If you notice any serious effects or other effects not mentioned in this package leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES
Cattle, sheep, goats 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 one subcutaneous injection site.

Sheep and goats
5 mg of enrofloxacin/kg bw, corresponding to 1 ml/20 kg bw, once daily by subcutaneous injection for 3 days.
Not more than 6 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 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.

Sheep:

Meat and offal: 4 days.
Milk: 3 days.

Goats:
Meat and offal: 6 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 freeze.

Store in the original package.

Do not use this veterinary medicinal product after the expiry date which is stated on the vial after EXP.

Protect from light

Shelf-life after first broaching the container: 28 days

12. 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.

Use of the product including use deviating from the instructions given in the SPC may increase the prevalence of bacteria resistant to enrofloxacin and may decrease the effectiveness of treatment with all 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 any contact with the product.

Avoid skin and eye contact. Wash any splashes from skin or eyes immediately with water.

Wash hands after use. Do not eat, drink or smoke whilst handling the product.

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

Other precautions

In countries where feeding of fallen stock to scavenger bird populations is permitted as a conservation measure (see Commission Decision 2003/322/EC), the possible risk to hatching success should be considered before feeding carcasses of livestock recently treated with this product.

Pregnancy and lactation

Cattle
The safety of the veterinary medicinal product has been established in pregnant cows during the 1st quarter of pregnancy. The product can be used in pregnant cows during the 1st quarter of pregnancy.
The use of the product in cows during the 3 last quarters of pregnancy should be based on a benefit-risk assessment by the responsible veterinarian.
The product can be used in cows during lactation.

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

Pigs
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.
The product can be used in sows during lactation.

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 pigs, no adverse effects were reported after the administration of 5 times the recommended dose.

In cattle, sheep and goat, overdose has not been documented.

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 veterinary medicinal products

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

Medicines should not be disposed of via wastewater or household waste.
Ask your veterinary surgeon 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

Amber polypropylene vials of 50, 100 and 250 ml provided with a grey (50 ml and 100 ml) or pink (250 ml) rubber-butyl stopper and aluminium capsule with a green Flip-Off sealing.

Not all pack sizes may be marketed.