ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Individual boxes for 50 ml, 100 ml and 250 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:
Enrofloxacin 100 mg

3. PACKAGE SIZE

50 ml, 100 ml and 250 ml

4. TARGET SPECIES

Cattle, sheep, goats and pigs.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Bovine: Subcutaneous/intravenous administration
Sheeps and goats: Subcutaneous administration
Porcine: Intramuscular administration

7. 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.

Sheep:

Meat and offal: 4 days.

Milk: 3 days.

Goats:

Meat and offal: 6 days.

Milk: 4 days.

Pigs:

Meat and offal: 13 days.

8. EXPIRY DATE

Exp. {mm/yyyy}

Once opened, use within 28 days. Once opened, use by …

PL:Termin ważności (EXP)

9. SPECIAL STORAGE PRECAUTIONS

Do not freeze. Store in the original package in order to protect from light.

10. THE WORDS "READ THE PACKAGE LEAFLET BEFORE USE"

Read package leaflet before use

11. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

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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

SP VETERINARIA SA

14. MARKETING AUTHORISATION NUMBERS

15. BATCH NUMBER

Lot{number}

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. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Enrofloxacin 100.0 mg/ ml

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

Once opened use within 28 days.

Once opened, use by …

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.

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE
Vials of 100 and 250 ml.

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:

Enrofloxacin 100.0 mg

3. TARGET SPECIES

Cattle, sheep, goats and pigs.

4. ROUTES OF ADMINISTRATION

Solution for injectionRead the package leaflet before use.

5. 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.

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. EXPIRY DATE

Exp. {mm/yyyy}
Once opened use within 28 days.
Once opened, use by …

7. SPECIAL STORAGE PRECAUTIONS

Do not freeze.
Store in the original package in order to protect from light.

8. NAME OF THE MARKETING AUTHORISATION HOLDER

SP VETERINARIA SA

9. BATCH NUMBER

Lot {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

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

2. Composition

Active substance:
Enrofloxacin 100.0 mg

Excipients :
n-Butyl alcohol 30 mg

Clear yellow solution

3. Target species

Cattle, goat, pig, sheep

4. Indications for use

Cattle

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

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

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

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

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

Sheep

Treatment of infections of the alimentary tract caused by strains of *Escherichia coli*.
Treatment of septicaemia caused by strains of *Escherichia coli*.
Treatment of mastitis caused by strains of *Staphylococcus aureus* and *Escherichia coli*.

Goats

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

Pigs

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

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

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

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

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

5. Contraindications

Do not use in cases of hypersensitivity to the active substance or other 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

Cross-resistance within the fluoroquinolone class of antimicrobials is common.

Special precautions for safe use in the target species:
Use of the product should be based on identification and susceptibility testing on the target pathogen(s). If this is not possible, therapy should be based on epidemiological information and knowledge of susceptibility of the target pathogens at farm level, or at local/regional level.
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 should be in accordance with official, national and regional antimicrobial policies.
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 contact with the veterinary medicinal product.
Avoid skin and eye contact. In case of accidental spillage onto skin or eyes, wash them 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. In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician
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

Major incompatibilities:

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

Special restrictions for use and special conditions for use:

For administration only by a veterinarian

7. Adverse events

Cattle:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):
Digestive tract disorders (e.g. diarrhoea) (generally mild and transient), circulatory shock (intravenous treatment can cause shock reactions, presumably as a result of circulatory impairment.)

Sheep and goats:

Very rare

(<1 animal / 10,000 animals treated, including isolated reports):
Digestive tract disorders (e.g. diarrhoea) (generally mild and transient).

Pigs:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):
Digestive tract disorders (e.g. diarrhoea) (generally mild and transient), application site disorders (may persists up to 28 days after the injection)

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 local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system.

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.

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.

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.

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.

Do not freeze.

Store in the original package in order to protect from light.

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

The expiry date refers to the last day of that month.

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

12. Special precautions for disposal

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.

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.

13. Classification of veterinary medicinal products

ES: Dispensing conditions: **Veterinary medicinal product subject to prescription**.

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

14. Marketing authorisation numbers and pack sizes

[MA number]

Package sizes:
1 vial of 50 ml
1 vial of 100 ml
1 vial of 250 ml

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

DD/MM/YYYY

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

16. Contact details

Marketing authorisation holder and manufacturer responsible for batch release:

SP VETERINARIA S.A.
Ctra. Reus-Vinyols, km 4,1
43330 Riudoms (SPAIN)

Local representatives and contact details to report suspected adverse reactions:

België/Belgique/Belgien	**Luxembourg/Luxemburg**
{Nom/Naam/Name}	{Nom}
<{Adresse/Adres/Anschrift }	<{Adresse}
BE-0000 {Localité/Stad/Stadt}>	L-0000 {Localité/Stadt}>
Tél/Tel: + {N° de téléphone/Telefoonnummer/	Tél/Tel: + {N° de téléphone/Telefonnummer}
Telefonnummer}	<{E-mail}>
<{E-mail}>	

Deutschland

{Name}

<{Anschrift}

DE-00000 {Stadt}>

Tel: + {Telefonnummer}

<{E-mail}>

Nederland

{Naam}

<{Adres}

NL-0000 XX {stad}>

Tel: + {Telefoonnummer}

<{E-mail}>

Република България

{Наименование}

<{Адрес}

BG {Град} {Пощенски код}>

Тел: + 359 {Телефонен номер}

<{E-mail}>

Magyarország

{Név}

<{Cím}

HU-0000 {Város}>

Tel.: + {Telefonszám}

<{E-mail}>

Ελλάδα

{Όνομα}

<{Διεύθυνση}

EL-000 00 {πόλη}>

Τηλ: + {Αριθμός τηλεφώνου}

<{E-mail}>

España

{Nombre}

<{Dirección}

ES-00000 {Ciudad}>

Tel: + {Teléfono}

<{E-mail}>

Portugal

{Nome}

<{Morada}

PT-0000–000 {Cidade}>

Tel: + {Número de telefone}

<{E-mail}>

Polska

{Nazwa/ Nazwisko:}

<{Adres:}

PL – 00 000{Miasto:}>

Tel.: + {Numer telefonu:}

<{E-mail}>

Italia

{Nome}

<{Indirizzo}

IT-00000 {Località}>

Tel: + {Numero di telefono}>

<{E-mail}>

România

{Nume}

<{Adresă}

{Oraş} {Cod poştal} – RO>

Tel: + {Număr de telefon}

<{E-mail}>

17. Other information