ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE
Individual boxes for a vial of 100 ml and 250 ml

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE
Labels for vials of 100 ml and 250 ml and for boxes containing 10 vials of 100 ml or 250 ml

ES:O

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

UNOFLOX 100 mg/ml SOLUTION FOR INJECTION
Enrofloxacin

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:

Active substance:
Enrofloxacin .....100 mg

3. PHARMACEUTICAL FORM

BOX: Solution for injection

4. PACKAGE SIZE

1 x 100 ml
1 x 250 ml
10 vials x 100 ml
10 vials x 250 ml

5. TARGET SPECIES

Cattle and pigs

6. INDICATIONS

7. METHOD AND ROUTES OF ADMINISTRATION

Read the package leaflet before use.

8. WITHDRAWAL PERIODS

Cattle:
Meat and offal: s.c. 14 days
i.v.: 7 days
Milk: s.c.: 120 hours (5 days)

i.v.: 72 hours (3 days)

Pig:
Meat and offal: i.m.: 12 days.

9. SPECIAL WARNINGS, IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Once opened use within 28 days

11. SPECIAL STORAGE CONDITIONS

Do not freeze. Keep the container in the outer carton.

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

BOX: Any unused veterinary medicinal product or waste materials 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 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 (SPAIN)
Tel: 34977850170 – Fax: 34977850405

16. MARKETING AUTHORISATION NUMBER

17. MANUFACTURER'S BATCH NUMBER

Batch {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET:

UNOFLOX 100 mg/ml SOLUTION FOR INJECTION

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 manufacturing authorization holder responsible for batch release:
SP VETERINARIA SA
Ctra Reus Vinyols km 4.1
43330 - Riudoms (SPAIN)
Tel: 34977850170 – Fax: 34977850405

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

UNOFLOX 100 mg/ml SOLUTION FOR INJECTION
Enrofloxacin

3. STATEMENT OF THE ACTIVE SUBSTANCE AND OTHER INGREDIENTS

Each ml contains:

Active substance:
Enrofloxacin .....100 mg
Excipients:
n-Butanol .....30 mg
Benzyl alcohol (E1519) .....20 mg

Clear, yellow solution.

4. INDICATIONS

Cattle:
For the treatment of respiratory tract infections caused by enrofloxacin-sensitive *Histophilus somni*, *Mannheimia haemolytica, Pasteurella multocida* and *Mycoplasma* spp.
For the treatment of Mastitis caused by enrofloxacin-sensitive *E.coli*.

Pigs:
For the treatment of bacterial bronchopneumonia caused by enrofloxacin-sensitive *Actinobacillus pleuropneumoniae, Pasteurella multocida* and *Haemophilus parasuis*.

5. CONTRAINDICATIONS

Do not use in cases of hypersensitivity to the active substance or to any of the excipient.
Do not use in animals with central nervous system-associated seizure disorders.
Do not use in the presence of existing disorders of cartilage development or musculoskeletal damage around functionally significant or weight-bearing joints.
Do not use in case of resistance against other fluoroquinolone due to the potential for cross-resistance.

6. ADVERSE REACTIONS

Transitory inflammatory reactions (swelling, redness) can occur at the injection site in very rare cases. These regress within a few days without further therapeutic measures.
Intravenous treatment can cause shock reactions in cattle, probably as a result of circulatory disturbances, in very rare cases.
Gastrointestinal disturbances may occur in very rare cases during treatment of calves.

The frequency of adverse reactions is defined using the following convention:

- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

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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 inform your veterinary surgeon.

7. TARGET SPECIES

Cattle and pigs.

8. DOSAGE FOR EACH SPECIES, ROUTES AND METHOD OF ADMINISTRATION

Cattle
The dosage for respiratory disease is 7.5 mg enrofloxacin per kg body weight (BW) for a single treatment by subcutaneous administration (s.c.).
This is equivalent to 7.5 ml of the product per 100 kg bw and day.
Do not administer more than 15 ml (cattle) or 7.5 ml (calf) per injection site (s.c.).
In case of serious or chronic respiratory disease a second injection may be required after 48 hours.

The dosage for the treatment of colimastitis is 5 mg enrofloxacin per kg body weight (bw) by intravenous administration (i.v.).
This is equivalent to 5 ml of the product per 100 kg bw and day.
The treatment of colimastitis should be exclusively by intravenous application on 2 to 3 consecutive days.

Pigs
The dosage for respiratory tract infections is 7.5 mg enrofloxacin per kg body weight for a single administration.
This is equivalent to 0.75 ml of the product per 10 kg bw and day.
Do not administer more than 7.5 ml per injection site (intramuscular).
In case of serious or chronic respiratory disease a second injection may be required after 48 hours.

9. ADVICE ON CORRECT ADMINISTRATION

Cattle
For subcutaneous injection (respiratory disease) or for intravenous injection (colimastitis).

Pig
For intramuscular injection into the neck muscles behind the ear.

To ensure administration of the correct dosage, body weight should be determined as accurately as possible to avoid underdosing.
The stopper may be safely punctured up to 30 times.

10. WITHDRAWAL PERIODS

Cattle:
Meat and offal: s.c. 14 days
i.v.: 7 days
Milk: s.c.: 120 hours (5 days)
i.v.: 72 hours (3 days)

Pig:
Meat and offal: i.m.: 12 days.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Do not freeze. Keep the container in the outer carton.
Do not use this veterinary medicinal product after the expiry date which is stated on the label.

12. SPECIAL WARNINGS

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.
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.
For repeated injection or for injection volumes exceeding 15 ml (cattle) or 7.5 ml (pigs, calves) in divided doses, a new site must be chosen for each injection.
Enrofloxacin is eliminated renally. As with all fluoroquinolones, delayed excretion can therefore be expected in the presence of existing renal damage.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
Direct contact with the skin should be avoided due to sensitisation, contact dermatitis and possible hypersensitivity reactions.
People with known hypersensitivity to (fluoro)quinolones should avoid contact with the product.
Wash hands after use.
In the event of accidental splash into the eye, rinse with large amounts of clean water. If irritation occurs, seek medical advice.
Do not eat, drink or smoke while handling the product.

Take care to avoid accidental self-injection.
In case of accidental self-injection, seek medical advice immediately and show the package leaflet or label to the physician.

Pregnancy and lactation:
May be used during pregnancy and lactation

Interaction with other medicinal products and other forms of interaction:
Antagonist 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):
In cattle a dose of 25 mg/kg bodyweight administered by the subcutaneous route for 15 consecutive days is tolerated without any clinical symptoms. Higher doses in cattle and doses of around 25 mg/kg and above in pig may cause lethargy, lameness, ataxia, slight salivation and muscle tremors.

Do not exceed the recommended dose. In accidental overdose there is no antidote and treatment should be symptomatic.

Incompatibilities:
In the absence of incompatibility 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 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

[mm/yyyy]

15. OTHER INFORMATION

Pack sizes: Boxes containing 1 vial of 100 ml
Boxes containing 1 vial of 250 ml
Boxes containing 10 vials of 100 ml
Boxes containing 10 vials of 250 ml

Not all pack sizes may be marketed.

Veterinary use – to be supplied only on veterinary prescription
Administration by a veterinarian surgeon (in case of intravenous route) or under their direct responsibility.