ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:

Enrofloxacin	100.0 mg

3. PACKAGE SIZE

50 ml, 100 ml and 250 ml

4. TARGET SPECIES

Cattle and pigs.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Cattle: Subcutaneous/intravenous administration

Pigs: Intramuscular administration

7. WITHDRAWAL PERIODS

Withdrawal period:

Cattle:

Following intravenous injection:

Meat and offal: 5 days.

Milk: 72 hours.

Following subcutaneous injection:

Meat and offal: 12 days.

Milk: 96 hours.

Pigs:

Meat and offal: 13 days.

8. EXPIRY DATE

Exp. { mm/yyyy }>

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

Once broached, use by _____

9. SPECIAL STORAGE PRECAUTIONS

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

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only

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

GLOBAL VET HEALTH SL

14. MARKETING AUTHORISATION NUMBER(S)

Vm 36167/3001

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Amber polypropylene vials of 50ml provided with a grey 50 ml rubber-butyl stopper and aluminium seal with a green Flip-Off sealing.

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Quinoflox 100 mg/ml

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Enrofloxacin	100.0 mg/ml

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}
Once broached, use before _____
Shelf life after first opening the container: 28 days

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

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

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Quinoflox 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 and pigs.

4. ROUTES OF ADMINISTRATION

Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Withdrawal period:

Cattle:

Following intravenous injection:

Meat and offal: 5 days.

Milk: 72 hours.

Following subcutaneous injection:

Meat and offal: 12 days.

Milk: 96 hours.

Pigs:

Meat and offal: 13 days.

6. EXPIRY DATE

Exp. {mm/yyyy}

Once broached, use before _____

Shelf life after first opening the container: 28 days

7. SPECIAL STORAGE PRECAUTIONS

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

8. NAME OF THE MARKETING AUTHORISATION HOLDER

GLOBAL VET HEALTH SL

9. BATCH NUMBER

Lot {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

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

2. Composition

Each ml contains:

Enrofloxacin	100.0 mg
Benzyl alcohol	0.02 ml

Clear yellow solution

3. Target species

Cattle and pigs

4. Indications for use

Cattle

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

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

Treatment of septicaemia caused by *Escherichia coli*.

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

Pigs

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

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

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

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

Treatment of septicaemia caused by *Escherichia coli*.

5. Contraindications

Do not use in case of hypersensitivity to the active substance or to any of the excipients.
Do not use in growing horses because of possible deleterious damage on articular cartilage.
Do not use in animals with central nervous system-associated seizure disorders.

6. Special warnings

Special warnings:

None.

Special precautions for safe use in the target species:
Degenerative changes of articular cartilage were observed in calves treated orally with 30 mg enrofloxacin/kg bw during 14 days.

Do not use in the presence of existing disorders of cartilage development or musculoskeletal damage around functionally significant or weight-bearing joints.

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.
Use of the product should be in accordance with official, national and regional antimicrobial policies.
Use of the product should be based on identification and susceptibility testing of 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 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.
An antibiotic with a lower risk of antimicrobial resistance selection (lower AMEG category) should be used for first line treatment where susceptibility testing suggests the likely efficacy of this approach.
The feeding of waste milk containing residues of enrofloxacin to calves should be avoided up to the end of the milk withdrawal period (except during the colostral phase), because it could select antimicrobial-resistant bacteria within the intestinal microbiota of the calf and increase the faecal shedding of these bacteria.

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.
Direct contact with the skin should be avoided because of sensitisation, contact dermatitis and possible hypersensitivity reactions to fluoroquinolones.
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 veterinary medicinal 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.

Special precautions for the protection of the environment:
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 veterinary medicinal 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 veterinary medicinal product can be used in pregnant cows during the 1st quarter of pregnancy.
The use of the veterinary medicinal product in cows during the 3 last quarters of pregnancy should be based on a benefit-risk assessment by the responsible veterinarian.
The veterinary medicinal product can be used in cows during lactation.

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 veterinary medicinal 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:
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 overdose has not been documented.
In accidental overdose there is no antidote and treatment should be symptomatic.

Special restrictions for use and special conditions for use:

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

7. Adverse events

Cattle

Very rare (<1 animal / 10,000 animals treated, including isolated reports):
Digestive tract disorders (e.g. diarrhoea)[1], and Circulatory shock.[2]

[1]These signs are generally mild and transient.
[2]As a result of circulatory impairment following intravenous treatment.

Pigs

Very rare (<1 animal / 10,000 animals treated, including isolated reports):
Digestive tract disorders (e.g. diarrhoea)[1], and Injection site reaction and, Injection site inflammation.[3]

[1]These signs are generally mild and transient.
[3]After intramuscular administration. They may persist 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 {national system details}.

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 *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 veterinary medicinal 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.

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: 72 hours.

Following subcutaneous injection:

Meat and offal: 12 days.

Milk: 96 hours.

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 temperature storage conditions.
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 label. 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.

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. These measures should help to protect the environment.

UK(NI): Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirement.

Ask your veterinary surgeon how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

August 2023

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

16. Contact details

Marketing authorisation holder:
Global Vet Health S.L.
Calle Capcanes 12 Bajos
Poligon Agro-Reus
43206 Reus
Spain

Manufacturer responsible for batch release:
SP VETERINARIA SA
Ctra Reus Vinyols km 4.1
Riudoms (43330)
Spain

Local representatives and contact details to report suspected adverse reactions:
DUGV (UK) Ltd
Union House
111 New Union Street
Coventry
Warwickshire
CV1 2NT
Tel: + 353 (0) 504 43169

17. 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 seal with a green Flip-Off sealing.

Approved 18 August 2023