PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE AND OUTER PACKAGE

Label - leaflet

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

Marketing authorisation holder
GLOBAL VET HEALTH SL
C/Capçanes
nº12-bajos
Polígono Agro-Reus
REUS 43206
(SPAIN)

Manufacturer responsible for batch release:

SP VETERINARIA SA
Ctra Reus Vinyols km 4.1
Riudoms (43330)
Tarragona (SPAIN)

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Quinoflox 100 mg/ml solution for use in drinking water for chickens and rabbits

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

Each ml of the product contains:

Active substance:
Enrofloxacin 100 mg

Excipients:
Benzyl alcohol (E 1519) 14.6 mg

Clear yellow solution for use in drinking water.

4. INDICATIONS

Chickens (Broilers, replacement chickens, broiler breeders):
Treatment of infections caused by the following bacteria susceptible to enrofloxacin:

Mycoplasma gallisepticum,
Mycoplasma synoviae,
Avibacterium paragallinarum,
Pasteurella multocida

Rabbits: Treatment of respiratory infections caused by *P. multocida* susceptible to enrofloxacin.

Where clinical experience, supported where possible by sensitivity testing of the causal organism, indicates enrofloxacin as the drug of choice.

5. CONTRAINDICATIONS

Do not use in case of renal and hepatic failure.
Do not treat animals with cartilaginous growth disturbance.
Do not use in case of known hypersensitivity to the active substance, other (fluoro)quinolones or to any of the excipients.
Do not use for prophylaxis.
Do not use when resistance/ cross-resistance to (fluoro)quinolones is known to occur in the flock intended for treatment.

See section 10

6. ADVERSE REACTIONS

In very rare cases adverse reactions appear in young animals at articular level, at the central nervous system and urinary and digestive tracts.

In very rare cases, during the period of rapid growth, enrofloxacin may affect articular cartilage.

The frequency of adverse reactions is defined using the following convention:
- Very common (more than 1 in 10 animals displaying adverse reaction(s) 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).

7. TARGET SPECIES

Chickens (Broilers, replacement chickens, broiler breeders) and rabbits

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

In drinking water use.

10 mg enrofloxacin/kg bodyweight per day for 3-5 consecutive days.
Treatment for 3-5 consecutive days; for 5 consecutive days in mixed infections and chronic progressive forms and rabbits. If no clinical improvement is achieved within 2-3 days, alternative antimicrobial therapy should be considered based on susceptibility testing.

For the preparation of medicated water the body weight of the animals to be treated and their actual daily water consumption should be taken into account. Consumption may vary depending on factors like age, state of health, breed, husbandry system. To provide the required amount of veterinary medicinal product in ml per litre drinking water the following calculation should be made:

$$\frac{\text{0.1ml of the product per kg bodyweight daily} \times \text{average bodyweight (kg) of the animals to be treated} \times \text{number of animals}}{\text{Total water consumption (l) of the herd at the previous day}} = \text{ml of the product per litre drinking water}$$

Sufficient access to the system of water supply should be available for the animals to be treated to ensure adequate water consumption. No other source of drinking water should be available during the medication period. Care should be taken that the intended dose is completely ingested. Use appropriate and properly calibrated dosing equipment.

If there is no clinical improvement within 3 days the treatment approach should be reconsidered. After the end of the medication period the water supply system should be cleaned appropriately to avoid intake of sub-therapeutic amounts of the active substance which might support development of resistance.
Medicated drinking water should be replaced every 24 hours.

9. ADVICE ON CORRECT ADMINISTRATION

Taking into account the way of administration of the product and that the uptake of water depends on the clinical condition of the animals, to assure a correct dosage the concentration of the product should be adjusted on the basis of the daily feed and water consumption.

10. WITHDRAWAL PERIOD

Meat and offal:

Chickens	7 days
Rabbits	2 days

Not authorised for use in birds producing eggs for human consumption.

Do not administer to layer replacement birds within 14 days of coming into lay.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Protect from light

Shelf-life after dilution or reconstitution according to directions: 24 hours
Shelf-life after first opening the container: 3 months
EXP {month/year}
PL: Termin ważności (EXP)

Once opened, use by: _____
Do not use this veterinary medicinal product after the expiry date which is stated on the label after EXP. The expiry date refers to the last day of that month

12. SPECIAL WARNINGS

Special warnings for each target species

Treatment of *Mycoplasma spp* infections may not eradicate the organism.

Special precautions for use

i) Special precautions for use in animals

Since enrofloxacin was first authorised for use in poultry, there has been widespread reduction in susceptibility of *E.coli* to fluoroquinolones and emergence of resistant organisms. Resistance has also been reported in *Mycoplasma synoviae* in the EU.
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.
Wherever possible, fluoroquinolones should be used based on susceptibility testing.
Use of the product deviating from instructions given in the SPC may increase the prevalence of bacteria resistant to fluoroquinolones and may decrease the effectiveness of treatment with other quinolones due to the potential for cross resistance.
After the end of treatment, the watering system should be cleaned appropriately to prevent the intake of remaining subtherapeutic doses of the drug, which may lead to resistance

Before use, header tanks should be emptied, thoroughly cleaned and then filled with a known volume of clean water before adding the required amount of product. The resulting mixture should be stirred.

Before use, header tanks should be inspected at regular intervals for presence of dust, algae formation and sedimentation.

If there is no clinical improvement within two to three days susceptibility testing should be repeated and therapy should be changed, if appropriate.

ii) Special precautions to be taken by the person administering the product to the animals

This product is an alkaline solution; personal protective equipment, including impervious gloves, should be worn when handling the product.

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

In the event of eye or skin contact, rinse the affected area with clean water and if irritation occurs, seek medical attention.

People with known hypersensitivity to (fluoro)quinolones should avoid contact with the product.

Wash hands and exposed skin after use.

Do not eat, drink or smoke whilst using the product.

Use during pregnancy, lactation or lay

The safety of the veterinary medicinal product has not been established during pregnancy and lactation in rabbits. Laboratory studies in rabbits have not produce any evidence of a teratogenic, foetoxic or maternotoxic effects. Use only accordingly to the benefit/risk assessment by the responsible veterinarian.
Do not use within 14 days before start of the laying period.

Interaction with other medicinal products and other forms of interaction

Concurrent use of enrofloxacin with other antimicrobials, tetracyclines and macrolide antibiotics, may result in antagonistic effects.

Absorption of enrofloxacin may be reduced if the product is administered together with substances containing magnesium or aluminium.
Enrofloxacin may alter the hepatic metabolism of co-administered products.
Do not administer with non steroidal anti-inflammatory products.

Overdose (symptoms, emergency procedures, antidotes if necessary)

At the dosage of 20mg/kg b.w. (twice the recommended dosage) administered in rabbits for 15 days (3 times the recommended duration of treatment) adverse reactions were not observed. In case of overdosage, the symptoms would be convulsions and the treatment should be ceased.
In case of considerable overdose in chickens intoxication by fluoroquinolones may cause nausea, vomiting and diarrhoea .
In accidental overdose there is no antidote and treatment should be symptomatic.

Incompatibilities

This veterinary medicinal product must not be mixed with other veterinary medicinal products.

Increased influx of the air (admixing CO_2 from the air) into medicated drinking water may result in precipitation of enrofloxacin.
Precipitation of the salt of enrofloxacin and alkalis may occur at higher concentration of calcium and magnesium in the water system during intermediate dilution in the dosage devices.

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

Medicines should be not 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 LABEL WAS LAST APPROVED

15. OTHER INFORMATION

Presentations: 12 x 1 L in cardboard box and 4 x 5 L in cardboard box 1 L
5 L
Not all pack sizes may be marketed.

For animal treatment only - to be supplied only on veterinary prescription.

IT: Da vendersi dietro presentazione di ricetta medico-veterinaria in triplice copia non ripetibile

PL: (For animal treatment only - to be supplied only on veterinary prescription).

Wyłącznie dla zwierząt.

Wydawany z przepisu lekarza – Rp. Do podawania pod nadzorem lekarza weterynarii

MARKETING AUTHORISATION NUMBER

Vm 36167/4001

MANUFACTURER'S BATCH NUMBER

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

Approved 04 July 2018