

Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

SPECTRON 100 mg/ml solution for use in drinking water for chickens and turkeys

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:

Enrofloxacin..... 100 mg

For the full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Solution for use in drinking water. Slightly yellowish clear solution.

4 CLINICAL PARTICULARS

4.1 Target Species

Chickens and Turkeys.

4.2 Indications for use, specifying the target species

Treatment of infections caused by the following bacteria susceptible to enrofloxacin:

Chickens

Mycoplasma gallisepticum,
Mycoplasma synoviae,
Avibacterium paragallinarum,
Pasteurella multocida.

Turkeys

Mycoplasma gallisepticum,
Mycoplasma synoviae,
Pasteurella multocida.

4.3 Contraindications

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.

Do not use in case of known hypersensitivity to the active substance, to other (fluoro)quinolones, or to any of the excipients.

4.4 Special warnings for each target species

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

4.5 Special precautions for use

Special precautions for use in animals

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 the veterinary medicinal product. The resulting mixture should be stirred.

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 product deviating from the 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.

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.

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.

Special precautions to be taken by the person administering the veterinary medicinal product to 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 fluoroquinolones should avoid contact with the product.

Wash hands and exposed skin after use.

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

4.6 Adverse reactions (frequency and seriousness)

None known.

4.7 Use during pregnancy, lactation or lay

Do not use in laying birds producing eggs for human consumption.

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

4.8 Interaction with other medicinal products and other forms of interaction

In vitro, an antagonism was shown, when combining fluoroquinolones with bacteriostatic antimicrobial agents such as macrolides or tetracyclines and phenicols. The simultaneous application of substances containing aluminium or magnesium can impair the absorption of enrofloxacin.

Do not combine enrofloxacin with steroidal anti-inflammatory products.

4.9 Amounts to be administered and administration route

For oral administration via the drinking water. This may be put directly into the header tanks, or via water proportioner systems.

Chickens and turkeys

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. If no clinical improvement is achieved within 2-3 days, alternative antimicrobial therapy should be considered based on susceptibility testing.

Medication of the water supply should be continuous during the treatment period and no other source of water should be available.

Medicated water should be made every day, immediately prior to provision. Carefully calculate the total body mass to be treated and the total daily water consumption before each treatment.

The uptake of medicated water depends on age and clinical condition of the birds, ambient temperature, and light regime. In order to obtain the correct dosage the concentration of the product should be adjusted accordingly. Taking into consideration that 10 mg enrofloxacin per kg body weight corresponds to 0.1 ml of the product per kg body weight; the following calculation should be made to provide the required amount of the product per litre of drinking water:

$$\frac{0.1 \times \text{Average bodyweight of birds to be treated (kg)} \times \text{Number of birds}}{\text{Total water consumption (l) of the flock at the previous day}} = \text{ml product per litre of drinking water}$$

Care should be taken that the intended dose is completely ingested.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

No adverse clinical symptoms were observed in chickens and turkeys treated respectively with doses up to 10 and 6 times higher than the therapy dose.

The use of fluoroquinolones during the growth phase combined with a marked and prolonged increase in the intake of drinking water, and hence active ingredient, possibly due to high temperatures, may potentially be associated with damage of the articular cartilage.

4.11 Withdrawal period(s)

Chickens: Meat and offal: 7 days.

Turkeys: Meat and offal: 13 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.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: quinolone and quinoxaline antibacterials, fluoroquinolones.

ATCvet code: QJ01MA90

5.1 Pharmacodynamic properties

Mode of action

Two enzymes essential in DNA replication and transcription, DNA gyrase and topoisomerase IV, have been identified as the molecular targets of fluoroquinolones. They modulate the topological state of DNA through cleaving and resealing reactions. Initially, both strands of the DNA double helix are cleaved. Then, a distant segment of DNA is passed through this break before the strands are resealed. Target inhibition is caused by non-covalent binding of fluoroquinolone molecules to an intermediate state in this sequence of reactions, in which DNA is cleaved, but both strands are retained covalently attached to the enzymes. Replication forks and translational complexes cannot proceed beyond such enzyme-DNA-fluoroquinolone complexes, and inhibition of DNA and mRNA synthesis triggers events resulting in a rapid, drug concentration-dependent killing of pathogenic bacteria.

Antibacterial spectrum

Enrofloxacin is active against many Gram-negative bacteria, against Gram-positive bacteria and *Mycoplasma* spp.

In vitro susceptibility has been shown in strains of (i) Gram-negative species such as *Pasteurella multocida* and *Avibacterium (Haemophilus) paragallinarum* and (ii) *Mycoplasma gallisepticum* and *Mycoplasma synoviae*. (See section 4.5)

Types and mechanisms of resistance.

Resistance to fluoroquinolones has been reported to arise from five sources, (i) point mutations in the genes encoding for DNA gyrase and/or topoisomerase IV leading to alterations of the respective enzyme, (ii) alterations of drug permeability in Gram-negative bacteria, (iii) efflux mechanisms, (iv) plasmid mediated resistance and (v) gyrase protecting proteins. All mechanisms lead to a reduced susceptibility of the bacteria to fluoroquinolones. Cross-resistance within the fluoroquinolone class of antimicrobials is common.

5.2 Pharmacokinetic particulars

The pharmacokinetics of enrofloxacin are such that oral and parenteral administration leads to similar serum levels. Enrofloxacin possesses a high distribution volume. Tissue levels 2-3 times higher than that found in the serum, have been demonstrated in laboratory animals and target species. Organs in which high

levels can be expected are the lungs, liver, kidney, skin, bone and lymphatic system. Enrofloxacin also distributes into the cerebrospinal fluid and the aqueous humour. The degree of metabolism depends on the species and ranges between 50-60 %. Biotransformation at hepatic level of enrofloxacin results in the active metabolite, ciprofloxacin. In general, metabolism is by hydroxylation and oxidation processes to oxofluoroquinolones. Other reactions that also occur are N-dealkylation and conjugation with glucuronic acid. Excretion occurs by biliary and renal route, with excretion in the urine predominating.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Potassium hydroxide
n-Butanol
Purified water

6.2 Major incompatibilities

Do not mix with any other veterinary medicinal product.

6.3 Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale: 2 years
Shelf-life after first opening the immediate packaging: 3 months.
Shelf life after dilution according to directions: 24 hours.

6.4 Special precautions for storage

This veterinary medicinal product does not require any special temperature storage conditions.
Keep the bottle tightly closed.

6.5 Nature and composition of immediate packaging

The product is filled in 100 ml and 1 L high-density polyethylene bottles and 5 L high-density polyethylene barrels closed with a tamper-evident screw cap of the same material.
Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

Laboratorios Hipra S.A.
Avda. La Selva 135
17170 - Amer (Girona)
Spain

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10846/011/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 19th November 2010
Date of last renewal: 18th November 2015

10 DATE OF REVISION OF THE TEXT

July 2018