

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

FLOXAMAX 100 mg/ml concentrate for oral solution for chickens and turkeys

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substances:

Enrofloxacin..... 100 mg

Excipients:

Qualitative composition of excipients and other constituents	Quantitative composition if that information is essential for proper administration of the veterinary medicinal product
Potassium hydroxide	
Purified water	
Benzyl alcohol (E 1519)	0.014 ml

Clear yellow solution.

3. CLINICAL INFORMATION

3.1. Target species

Chickens and turkeys.

3.2. Indications for use for each target species

Treatment of infections caused by the following bacteria:

Chickens

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

Turkeys

Mycoplasma gallisepticum,
Mycoplasma synoviae,
Pasteurella multocida.

3.3. 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.

3.4. Special warnings

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

3.5. Special precautions for use

Special precautions for safe use in the target species:

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.

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.

Use of the product deviating from the instructions given by in the SPC may increase the prevalence of bacteria resistant to the fluoroquinolones and may decrease the effectiveness of treatment with other fluoroquinolones due to the potential for cross-resistance.

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.

Use of the product should be in accordance with official, national and regional antimicrobial policies.

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.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

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

Avoid contact with skin and eyes.

Rinse any splashes from skin or eyes immediately with water.

Wash hands and exposed skin after use.

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

Special precautions for the protection of the environment:

Not applicable.

3.6. Adverse events

None known.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing

authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7. Use during pregnancy, lactation or lay

Laying birds:

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

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

3.8. 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.

3.9. Administration routes and dosage

For administration in drinking water.

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.

Based on the recommended dose and the number and weight of animals to be treated, the exact daily concentration of the veterinary medicinal product should be calculated according to the following formula:

$$\frac{0.1 \text{ ml veterinary medicinal product/kg body weight / day} \times \text{average body weight of individual animals (kg)} \times \text{number of animals to be treated}}{\text{Total water intake (litres) of animals to be treated on the previous day}} = \text{ml of veterinary medicinal product per litre of drinking water}$$

The product may be put directly into the header tank or introduced via a water proportioner pump.

Always make sure that the entire dose offered has been consumed. The medicated water should be made up fresh each day just before it is offered to the animals. The drinking water must be medicated throughout the treatment period, and no other water source should be available. To ensure a correct dosage, body weight should be determined as accurately as possible.

Use only fresh pre-solutions, prepared every day before start of treatment. Pumping systems should be checked constantly to assure proper medication. Empty the water system and fill it with medicated water before starting the treatment.

3.10. Symptoms of overdose (and where applicable, emergency procedures and antidotes)

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.

3.11. Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12. Withdrawal periods

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.

4. PHARMACOLOGICAL INFORMATION

4.1. ATCvet code:

QJ01MA90

4.2. Pharmacodynamics

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 3.5)

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.

4.3. Pharmacokinetics

Enrofloxacin administered via drinking water to poultry is rapidly and very well absorbed with a bioavailability of approx. 90 %. Maximum plasma concentrations of 2 mg/L are reached within 1.5 hours after a single bolus dose rate of 10 mg/kg body weight with a total systemic availability of 14.4 mg·hr/L.

Enrofloxacin is eliminated from the body with a total body clearance of 10.3 mL/min·kg. If dosed as continuous drinking water medication (multiple dosing) steady-state concentrations of 0.5 mg (turkeys) to 0.8 mg (chicken) enrofloxacin per litre are achieved. A high mean volume of distribution (5 L/kg) indicates good tissue penetration of enrofloxacin. Concentrations in target tissues like lungs, liver, kidney, intestine and muscle tissue, exceed plasma concentrations by far. In poultry enrofloxacin is poorly metabolized to its active metabolite ciprofloxacin (approximately 5 %). Enrofloxacin is eliminated from the body at a half-life of 6 hours. Protein binding in poultry is approximately 25 %.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

No information is available on potential interactions or incompatibilities of this veterinary medicinal product administered orally by mixing into drinking water containing biocidal products, feed additives or other substances used in drinking water.

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

5.2 Shelf-life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.

Shelf life after dilution according to directions: 24 hours.

Shelf life after first opening the immediate packaging: 3 months.

5.3 Special precautions for storage

This veterinary medicinal product does not require any special storage conditions.

5.4 Nature and composition of immediate packaging

1 L and 5 L white high density polyethylene containers with a green screw cap of the same material.

Presentations: 1 L, 5 L.

Not all pack sizes may be marketed.

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

Medicines should not be disposed of via wastewater or household waste.

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 national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

SP Veterinaria, S.A.,

7. MARKETING AUTHORISATION NUMBER(S)

VPA10790/002/001

8. DATE OF FIRST AUTHORISATION

07/03/2008

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

20/11/2025

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

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