

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Quiflor 100 mg/ml solution for injection for cattle and pigs (sows)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml of solution for injection contains:

Active substance:

Marbofloxacin 100 mg

Excipients:

Disodium edetate 0.10 mg

Monothioglycerol 1 mg

Metacresol 2 mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Solution for injection.

Clear, greenish yellow to brownish yellow solution.

4. CLINICAL PARTICULARS

4.1 Target species

Cattle and pigs (sows).

4.2 Indications for use, specifying the target species

Cattle

Treatment of respiratory infections caused by sensitive strains of *Pasteurella multocida*, *Mannheimia haemolytica* and *Mycoplasma bovis*.

Treatment of acute mastitis caused by *Escherichia coli* strains sensitive to marbofloxacin during the lactation period.

Sows

Treatment of Metritis Mastitis Agalactia Syndrome caused by bacterial strains sensitive to marbofloxacin.

The product should only be used based on susceptibility testing.

4.3 Contraindications

Do not administer in animals with known hypersensitivity to marbofloxacin or any other quinolone or to any of the excipients.

Do not use in cases where the pathogen involved is resistant to other fluoroquinolones (cross resistance).

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

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.

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 of the skin and eyes with the product. In case of accidental spillage onto skin or eyes, rinse the affected area with large amounts of water.

Avoid accidental self-injection, since this can cause local irritation. In case of self-injection or ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.

Wash hands after use.

4.6 Adverse reactions (frequency and seriousness)

Administration by the intramuscular route may cause transient local reactions such as pain and swelling at the injection site and inflammatory lesions which persist at least 12 days after injection. However, in cattle, subcutaneous route was shown to be better tolerated locally than intramuscular route. Therefore, the subcutaneous route is recommended in heavy cattle.

4.7 Use during pregnancy, lactation or lay

Studies in laboratory animals (rats, rabbits) did not show any teratogenic, embryotoxic effects or any maternal toxicity of marbofloxacin.

Safety of the product has been shown in cows during gestation and in suckling pigs and calves when used in cows and sows.

In the case of use in the cow during lactation, see paragraph 4.11. Withdrawal Periods.

May be used in pregnant and lactating cows and sows.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

The recommended dosage is 2 mg/kg/day (1 ml/50 kg) in a single daily injection by intramuscular, subcutaneous or intravenous routes in cattle and by intramuscular route in pigs.

Treatment durations are 3 days in pigs and 3 to 5 days in cattle.

To ensure administration of a correct dose, body weight should be determined as accurately as possible, to avoid underdosing.

In order to reduce the risk of particulate contamination of the product, it is recommended that a draw-off needle be used to reduce the number of times the septum is punctured.

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

No sign of overdose has been observed after administration of 3 times the recommended dose.

Overdose may cause signs in the form of acute neurological disorders which would have to be treated symptomatically.

4.11 Withdrawal period(s)

Cattle:

Meat and offal: 6 days

Milk: 36 hours

Pigs (sows):

Meat and offal: 4 days

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antibacterials for systemic use, Fluoroquinolones, ATCvet code: QJ01MA93

5.1 Pharmacodynamic properties

Marbofloxacin is a synthetic, bactericidal antimicrobial, belonging to the fluoroquinolone group which acts by inhibition of DNA gyrase. It is effective against a wide range of Gram positive bacteria (in particular Staphylococci) and Gram negative bacteria (*Escherichia coli*, *Salmonella typhimurium*, *Campylobacter jejuni*, *Citrobacter freundii*, *Enterobacter cloacae*, *Proteus* spp., *Klebsiella* spp., *Actinobacillus pleuropneumoniae*, *Bordetella bronchiseptica*, *Mannheimia haemolytica*, *Pasteurella multocida*, *Histophilus* spp., *Moraxella* spp., *Pseudomonas*

aeruginosa) as well as *Mycoplasma* (*Mycoplasma bovis*, *Mycoplasma dispar*, *Mycoplasma hyopneumoniae*).

Resistance in *Streptococcus* may occur.

Resistance to fluoroquinolones occurs by chromosomal mutation with three mechanisms: decrease of the bacterial wall permeability, expression of efflux pump or mutation of enzymes responsible for molecule binding.

5.2 Pharmacokinetic particulars

After subcutaneous administration in cattle and pigs at the recommended dose of 2 mg/kg, marbofloxacin is readily absorbed and its bioavailability is close to 100%. It is weakly bound to plasma proteins (less than 10% in pigs and 30% in cattle), extensively distributed and in most tissues (liver, kidney, skin, lung, bladder, uterus, digestive tract) it achieves higher concentrations than in plasma.

In cattle, marbofloxacin is eliminated slowly in pre-ruminating calves ($t_{1/2 \beta} = 5-9$ h) predominantly in the active form in urine (3/4) and faeces (1/4).

In pigs, marbofloxacin is eliminated slowly ($t_{1/2 \beta} = 8-10$ h) predominantly in the active form in urine (2/3) and faeces (1/3).

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Metacresol
Disodium edetate
Monothioglycerol
Gluconolactone
Water for injections

6.2 Incompatibilities

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

6.3 Shelf life

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

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

6.4. Special precautions for storage

Store in the original package in order to protect from light.
Do not freeze.

6.5 Nature and composition of immediate packaging

Bottle (amber glass type II), bromobutyl rubber stopper, aluminium closure: 50 ml solution for injection, in a box.

Bottle (amber glass type II), bromobutyl rubber stopper, aluminium closure: 100 ml solution for injection, in a box.

Bottle (amber glass type II), bromobutyl rubber stopper, aluminium closure: 250 ml solution for injection, in a box.

Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal product 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

8. MARKETING AUTHORISATION NUMBER

9. DATE OF FIRST AUTHORISATION

10. DATE OF REVISION OF THE TEXT

May 2016

PROHIBITION OF SALE, SUPPLY AND/OR USE

Veterinary prescription.

Approved: 17 May 2016

A handwritten signature in black ink, consisting of a stylized, cursive 'R' followed by a horizontal line and a small flourish.