SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Quiflor S 100 mg/ml solution for injection for cattle (United Kingdom, Austria, Belgium, Germany, Denmark, Greece, Italy, Netherlands, Portugal, Czech Republic, Latvia, Lithuania, Slovak Republic)
Quiflor Single Dose 100 mg/ml solution for injection for cattle (Spain)

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.

4.2 Indications for use, specifying the target species

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

This 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.
Where 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.

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)

Fluroquinolones are known to induce arthropathies. Nevertheless, this effect has never been observed with marbofloxacin in cattle.
Administration by the intramuscular route may cause transient local reactions such as pain and swelling at the injection site and inflammatory lesions which may persist for at least 12 days after injection. No other adverse effect was observed on cattle.

4.7 Use during pregnancy, lactation or lay

Studies in laboratory animals (rats, rabbits) did not show any evidence of a teratogenic, embryotoxic or maternotoxic effect associated with the use of marbofloxacin. Safety of the product at 8 mg/kg has not been determined in pregnant cows or in suckling calves when used in cows. Use therefore according to the benefit/risk assessment carried out by the responsible veterinarian.

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 8 mg/kg body weight i.e. 2 ml/25 kg body weight in a single intramuscular injection.
If the volume to be injected is more than 20 ml, it should be divided between two or more injection sites.

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

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 such as acute neurological disorders which should be treated symptomatically.

4.11 Withdrawal period(s)

Cattle:
Meat and offal: 3 days
Milk: 72 hours

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 has a broad-spectrum activity *in vitro* against mycoplasma, Gram-positive and Gram-negative bacteria.
The marbofloxacin *in vitro* activity against pathogens isolated in 2004 from bovine respiratory diseases during a clinical field trial in France, Germany, Spain and Belgium, is good: MIC values are comprised between 0.015 and 0.25 µg/ml for *M. haemolytica* (MIC_{90} = 0.124 µg/ml; MIC_{50} = 0.025 µg/ml), between 0.004 and 0.12 µg/ml for *P. multocida* (MIC_{90} = 0.022 µg/ml; MIC_{50} = 0.009 µg/ml) and between 0.015 and 2 µg/ml for *Histophilus somni*. Strains with MIC ≤ 1 µg/ml are sensitive to marbofloxacin whereas strains with MIC ≥ 4 µg/ml are resistant to marbofloxacin. 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 a single intramuscular administration in cattle at the recommended dose of 8 mg/kg, the maximum plasma concentration of marbofloxacin (Cmax) is 7.3 µg/ml

reached in = 0.78h (Tmax). Binding to plasma proteins is about 30%. Marbofloxacin is eliminated slowly (T1/2β = 15.60h), predominantly in the active form in urine and faeces.

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: 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

KRKA, d.d., Novo mesto
Šmarješka cesta 6
8501 Novo mesto
Slovenia

8. MARKETING AUTHORISATION NUMBER

Vm: 01656/4061

9. DATE OF FIRST AUTHORISATION

19 December 2011

10. DATE OF REVISION OF THE TEXT

May 2016

PROHIBITION OF SALE, SUPPLY AND/OR USE

Veterinary prescription.

Approved: 17 May 2016