

## **SUMMARY OF PRODUCT CHARACTERISTICS**

### **1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Quiflor S 100 mg/ml solution for injection for cattle [AT, BE, CZ, DE, DK, GR, IT, LV, LT, NL, PT, SK, UK]

Quiflor Single Dose 100 mg/ml solution for injection for cattle [ES]

### **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)**

Fluoroquinolones 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<sub>90</sub> = 0.124 µg/ml; MIC<sub>50</sub> = 0.025 µg/ml), between 0.004 and 0.12 µg/ml for *P. multocida* (MIC<sub>90</sub> = 0.022 µg/ml; MIC<sub>50</sub> = 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 (C<sub>max</sub>) is 7.3 µg/ml reached in = 0.78h (T<sub>max</sub>). Binding to plasma proteins is about 30%. Marbofloxacin is eliminated slowly (T<sub>1/2β</sub> = 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**

## **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 'R' followed by a flourish.