

## **SUMMARY OF PRODUCT CHARACTERISTICS**

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

Marbosol 20 mg/ml solution for injection for calves and piglets

### **2. QUALITATIVE AND QUANTITATIVE COMPOSITION**

**1 ml solution for injection contains:**

Active substance:

Marbofloxacin            20 mg

Excipients:

Metacresol                2 mg

Monothioglycerol      0.50 mg

For full list of excipients, see section 6.1.

### **3. PHARMACEUTICAL FORM**

Solution for injection.  
Clear, yellow solution.

### **4. CLINICAL PARTICULARS**

#### **4.1 Target species**

Cattle (pre-ruminating calves), piglets

#### **4.2 Indications for use, specifying the target species**

##### **Pre-ruminating calves:**

For treatment and prevention of respiratory infections caused by marbofloxacin susceptible *Mannheimia haemolytica* and *Pasteurella multocida* strains, where the presence of the disease has been established in the group.

##### **Piglets:**

For the treatment of respiratory infections caused by marbofloxacin susceptible *Actinobacillus pleuropneumoniae*, *Mycoplasma hyopneumoniae* and *Pasteurella multocida* strains.

#### **4.3 Contraindications**

Do not use in case of bacterial infections with resistance to other (fluoro) quinolones (cross resistance).

Do not use in case of hypersensitivity to the active substance or to any of the excipients.

#### **4.4 Special warnings for each target species**

None

#### **4.5 Special precautions for use**

i. 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.

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

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

This medicine is associated with sensitization and contact dermatitis and therefore direct contact with the skin should be avoided.

In case of contact with the skin or eyes, rinse with large amounts of water.

Avoid accidental self-injection. In case of accidental self-injection, 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 may cause a painful swelling at the injection site that disappears after a few days.

Inflammatory lesions can persist 6 days in piglets and 12 days in calves.

#### **4.7 Use during pregnancy, lactation or lay**

Not applicable.

#### **4.8 Interaction with other medicinal products and other forms of interaction**

No NSAIDs may be given, except for tolafenamic acid, simultaneously or within 24 hours after each administration.

Fluoroquinolones may increase concentrations of theophylline if used concurrently. Coadministration with divalent and trivalent cations, such as products containing aluminium (e.g. sucralfate), iron, and calcium, may

decrease absorption. Do not mix in solution or in vials with albumin, calcium, iron, or zinc because chelation may occur. Marbofloxacin may be administered with other antibiotics and anaesthetic agents without evidence of drug interaction.

#### **4.9 Amounts to be administered and administration route**

##### **Pre-ruminating calves:**

Intramuscular, subcutaneous or intravenous (for the first administration only) use:

2 mg/kg bodyweight/day (1 ml/10 kg BW) for 3 – 5 days.

##### **Piglets:**

Intramuscular use:

2 mg/kg bodyweight/day (1 ml/10 kg BW) for 3 – 5 days.

Do not inject the product in the same place in neck area. Maximal injection volume per injection should not exceed 5.5 ml for calves and 3.0 ml for pigs.

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

The stopper should not be punctured more than 20 times, the user should choose the most appropriate vial size according to the target species to treat.

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

No signs of overdosage have been observed after administration of up to 3 times the recommended dose in calves and up to 5 times in pigs.

Signs such as neurological disorders may occur when the dose is exceeded. Such signs should be treated symptomatically.

#### **4.11 Withdrawal period(s)**

Meat and offal:

Pre-ruminating calves: 6 days

Piglets: 3 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. It acts by inhibition of DNA gyrase and has a broad-spectrum activity against Gram-positive bacteria (especially *Staphylococcus*) and against Gram-negative bacteria (*E. coli*, *Pasteurella multocida*, *Mannheimia haemolytica* and *Actinobacillus pleuropneumoniae*) as well as against *Mycoplasma* (*Mycoplasma hyopneumoniae*).

Cases of resistance have been observed in *Streptococcus*.

Strains with MIC  $\leq 1$   $\mu\text{g/ml}$  are sensitive to marbofloxacin whereas strains with MIC  $\geq 4$   $\mu\text{g/ml}$  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 subcutaneous or intramuscular administration at the recommended dose of 2 mg medicinal product/kg bodyweight, in cattle or pigs, marbofloxacin is readily absorbed and reaches maximal plasma concentrations of 1.5  $\mu\text{g/ml}$  in less than 1 hour. Its bioavailability is close to 100%.

Marbofloxacin is weakly bound to plasma proteins ( $< 10\%$  in pigs and  $< 30\%$  in cattle), and is extensively distributed in most tissues (liver, kidneys, skin, lungs, uterus) it achieves higher concentrations than in plasma.

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

Marbofloxacin is eliminated slowly in pigs ( $t_{1/2} = 8-10$  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  
Gluconolactone  
Mannitol  
Monothioglycerol  
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**

Keep the bottle in the outer carton in order to protect from light.  
This veterinary medicinal product does not require any special temperature storage conditions.

### **6.5 Nature and composition of immediate packaging**

50 ml and 100 ml amber glass bottles (Type II) with chlorobutyl rubber stopper, covered with an aluminum cap.

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**

CP-Pharma Handelsgesellschaft mbH  
Ostlandring 13  
31303 Burgdorf  
Germany

**8. MARKETING AUTHORISATION NUMBER**

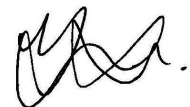
Vm 20916/4016

**9. DATE OF FIRST AUTHORISATION**

**Date:** 15 February 2013

**10. DATE OF REVISION OF THE TEXT**

**Date:** January 2015

A handwritten signature in black ink, consisting of stylized, overlapping loops and strokes, positioned above the approval text.

Approved: 26 January 2015