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 the 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

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 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 tolfenamic acid, simultaneously or within 24 hours after each administration.
Fluoroquinolones may increase concentrations of theophyline 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 andhas 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 µg/ml are sensitive to marbofloxacin whereas strains with MIC $\geq$ 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 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 µg /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 Major 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: 36 months.
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

To be completed nationally

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

To be completed nationally

10. DATE OF REVISION OF THE TEXT

PROHIBITION OF SALE, SUPPLY AND/OR USE

Administration by a veterinary surgeon or under their direct responsibility.
To be supplied only on veterinary prescription.