SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Marbosol 100 mg/ml solution for injection for cattle and pigs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1 ml solution for injection contains:

Active substance:
Marbofloxacin 100 mg

Excipients:
Metacresol 2 mg
Monothioglycerol 1 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, pigs

4.2 Indications for use, specifying the target species

Cattle:
Treatment of respiratory infections caused by susceptible strains of *Pasteurella multocida*, *Mannheimia haemolytica* and *Histophilus somni*.
Treatment of acute mastitis caused by *Echerichia coli* strains susceptible to marbofloxacin during the lactation period.

Pigs:
Treatment of Metritis Mastitis Agalactia Syndrome (MMA syndrome, postpartum dysgalactia syndrome, PDS) caused by bacterial strains susceptible to marbofloxacin.

4.3 Contraindications

Do not use in case of bacterial infections with resistance to other fluoroquinolones (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

Efficacy data have shown an insufficient efficacy of the product for the treatment of acute mastitis caused by Gram positive strains.

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 any 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)

Fluoroquinolones are known to induce arthropathies. Nevertheless, this effect has never been observed with marbofloxacin in cattle.
Intramuscular administration 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.

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 has not been determined in pregnant and lactating cows and sows. 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

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

Cattle:
Single dose (8 mg/kg) treatment of respiratory infections:

The recommended dosage is 8 mg/kg bodyweight/day (2 ml/25 kg BW) 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.

Multiple dose (2 mg/kg single daily injection, for 3 to 5 days) treatment of acute mastitis:
The recommended dosage is 2 mg/kg bodyweight/day (1ml/50kg BW) in a single daily injection by intramuscular, subcutaneous or intravenous (only the first injection) routes, for 3 - 5 consecutive days.

Pigs:
The recommended dosage is 2 mg/kg bodyweight/day (1ml/50kg BW) in a single daily injection by intramuscular route, for 3 consecutive days.

In cattle and pigs, the preferred site of injection is the neck.

To ensure 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 veterinary medicinal product, it is recommended that a draw-off needle be used to reduce the number of times the septum is punctured.

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 cattle 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)

Cattle:
Single dose (8 mg/kg) (IM)
Meat and offal: 3 days
Milk: 72 hours

Multiple dose (2 mg/kg single daily injection, for 3 to 5 days) (IV/SC/IM)
Meat and offal: 6 days
Milk: 36 hours

Pigs:
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 . Its acts by inhibition of DNA gyrase and has a broad-spectrumactivity against Gram positive bacteria and against Gram negative bacteria (*Escherichia coli, Pasteurella multocida, Mannheimia haemolytica* and *Histophilus somni*)
Cases of resistance have been observed in Streptococcus.
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 subcutaneous or intramuscular administration in cattle and intramuscular administration in pigs at the recommended dose of 2mg marbofloxacin/kg bodyweight, marbofloxacin is readily absorbed and reaches maximal plasma concentrations of 1.5µg/ml within less than 1 hour. 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 a higher concentration than in plasma.

In cattle, marbofloxacin is eliminated slowly in pre-ruminating calves ($t_{½}$ = 5-9h) but faster in ruminant cattle ($t_{½}$ = 4-7h) predominantly in the active form in urine (3/4 in pre-ruminating calves, 1/2 in ruminants) and faeces (1/4 in pre-ruminating calves, 1/2 in ruminants).
In pigs, marbofloxacin is eliminated slowly ($t_{½}$ = 8-10h) predominantly in the active form in urine (2/3) and faeces (1/3).

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Metacresol
Gluconolactone
Disodium edetate
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

To be completed nationally

<ES: Dispensing conditions: Veterinary medicinal product subject to prescription.
Administration conditions: Exclusive administration by the veterinary surgeon (in case of intravenous route).>