



100 mg/ml
Solution injectable
Marbofloxacin



COMPOSITION

Marbofloxacin.....	100.0 mg
Excipients q.s.	1.0 ml

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 Gram-negative bacteria (*Pasteurella multocida*, *Mannheimia haemolytica*, *Histophilus somni*, *E. coli*) and against Gram-positive bacteria (in particular *Staphylococcus*).

Resistance to *Streptococcus* may occur.

Strains with MIC $\leq$ 1 $\mu\text{g/ml}$ are sensitive to marbofloxacin whereas strains with MIC $>$ 2 $\mu\text{g/ml}$ 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.

PHARMACOKINETICS PARTICULAR

Cattle- Intramuscular route

After a single intramuscular administration at the recommended dose of 8 mg/kg, the maximum plasma concentration of marbofloxacin (C_{max}) is 8 $\mu\text{g/ml}$ reached in approximately 1 hour (T_{max}). Marbofloxacin is eliminated slowly (terminal T_{1/2} = 9.5 h), predominantly in the active form in urine and faeces.

Cattle- Subcutaneous route

After subcutaneous administration at the recommended dose of 2 mg/kg, marbofloxacin is readily absorbed and reaches maximal plasma concentrations of 1.7 $\mu\text{g/ml}$ in approximately 1 hour. The terminal elimination half-life (t_{1/2}) of marbofloxacin is 5.6 hours.

Pigs- Intramuscular route

After intramuscular administration at the recommended dose of 2 mg/kg, marbofloxacin is readily absorbed and reaches maximal plasma concentrations of 1.7 $\mu\text{g/ml}$ in approximately 1 hour. The terminal elimination half-life (t_{1/2}) of marbofloxacin is 8.7 hours.

Its bioavailability is close to 100 %.

Marbofloxacin 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) it achieves higher concentrations than in plasma.

Marbofloxacin is eliminated predominantly in the active form in urine and faeces.

TARGET SPECIES and INDICATIONS

Marbox® is indicated for cattle and pigs.

The indications for use are:

Cattle:

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

Therapeutic treatment of acute mastitis caused by *E. coli* strains sensitive to marbofloxacin during the lactation period.

Sows:

Treatment of Metritis Mastitis Agalactia Syndrome caused by bacterial strains sensitive to marbofloxacin.

DOSAGE AND ADMINISTRATION

Cattle:

Intramuscular use:

- Respiratory infections:

The recommended dosage is 8 mg/kg bodyweight i.e. 2 ml/25 kg bodyweight in a single injection.

If the volume to be injected is more than 20 ml, it should be divided between two or more injection sites.

Subcutaneous use:

- Acute mastitis:

The recommended dosage is 2 mg/kg i.e. 1 ml/50 kg bodyweight in a single daily injection, for 3 days.

The first injection may also be given by the intravenous route too.

Sows:

Intramuscular use:

The recommended dosage is 2 mg/kg i.e. 1 ml/50kg bodyweight in a single daily injection by intramuscular route, for 3 days. To ensure a correct dosage body weight should be determined as accurately as possible to avoid underdosing.



CONTRAINDICATION

Do not use in animals with known hypersensitivity to marbofloxacin or other quinolones.

Do not use in case of confirmed or suspected resistance to fluoroquinolones (cross resistance).

WITHDRAWAL PERIOD

Cattle:

Intramuscular: Meat and offal: 3 days. Milk: 72 hours.

Subcutaneous: Meat and offal: 6 days. Milk: 36 hours.

Sows:

Intramuscular: Meat and offal: 4 days.

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 2 mg/kg has been shown in cows during gestation and in suckling pigs and calves when used in sows and cows.

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.

ADVERSE EFFECTS

Administration by the intramuscular route may cause in cattle transient local reactions such as pain at the injection site and slight muscular inflammatory lesions (resulting in fibrosis). The process of cicatrisation starts rapidly (varying from fibrosis to synthesis of extracellular matrice and collagen) and may persist for at least 15 days after injection.

Administration by the subcutaneous route may induce slight to moderate oedema at the injection site. A moderate pain on palpation of the injection site occurred in some animals.

In pigs, administration by the intramuscular route may induce very transient slight oedema and mild inflammatory lesions at the injection site persisting for 12 days after injection.

For the injections, the neck should be preferred in cattle and pigs.

No other undesirable effects have been observed in cattle and pigs.

OVERDOSE AND TREATMENT

No sign of overdosage has been observed in cattle after administration of 3 times the recommended dose.

Overdosage may cause signs such as acute neurological disorders which should be treated symptomatically.

INCOMPATIBILITIES

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products

SPECIAL PRECAUTIONS FOR USE

I) Special precautions for use in animals

Use of the product should be based on susceptibility testing and has to take into account official and local antimicrobial policies. It is prudent to reserve the fluoroquinolones for the treatment of clinical conditions that have responded poorly, or are expected to respond poorly, to other classes of antibiotics.

Use of the product deviating from the instructions 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. As the vial cannot be broached more than 45 times, the user should choose the most appropriate vial size according to the target species to treat. For the injections, the neck should be preferred in cattle and pigs.

II) Special precautions to be taken by the person administering the veterinary medicinal product to animals

People with known hypersensitivity to (fluoro)quinolones should avoid any contact with the product. If the product comes into contact with the skin or eyes, rinse with copious amounts of water.

Take care to avoid accidental self-injection since it can induce a slight irritation. In case of accidental self-injection, seek medical advice immediately and show the package leaflet to the physician. Wash hands after use.

III) Others precautions

None.

PACKAGING SIZES

50ml, 100ml, 250ml, 500ml. (All packaging sizes are not necessarily commercially available).

STORAGE

Store below 30°C (room temperature), protected from light.

Once broached, it can be used within 28 days if kept at room temperature.

Keep out of reach of children.

Registered by:

Ceva Animal Health Malaysia Sdn Bhd

27-2, Oval Damansara.

No. 685, Jalan Damansara 60000 Kuala Lumpur.

Mfd by: Ceva Santé Animale, 10 Avenue De La Ballastière, 33500 Libourne

Controlled Medicine

FOR VETERINARY USE ONLY

NOT MARBOX 10% MY 200X160/FP 35,5X160 RECTO/VERSO CODE ARTICLE : 00000 BLACK	MARBOX 10% MALAISIE ID:67470 - 67471 - 67472 - 67473 CORPS : 8 pts
--	--

HELENE 05/10/20 - LOUIS 01/03/21 - 04/06/21
