MARBOFLOXAN 100

COMPOSITION:
Marbofloxacin 100 mg
Excipients up to 1 ml.

PHARMACOLOGICAL 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 (*Pasteurella multocida*, *Mannheimia haemolytica*, *Histophilus somni*, *E. coli*) and against Mycoplasma (*Mycoplasma bovis*). Resistance to *Streptococcus* may occur.
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.

TARGET SPECIES:
Cattle and pigs (sows).

INDICATIONS:
In cattle:
→ Treatment of respiratory infections caused by strains of *Histophilus somni*, *Mannheimia haemolytica*, *Mycoplasma bovis*, *Pasteurella multocida* susceptible for marbofloxacin.
→ Treatment of acute mastitis caused by strains of *Escherichia coli* susceptible to marbofloxacin during the lactation period.

In pigs:
→ Treatment of Postpartum Dysgalactia Syndrome – PDS – (Metritis Mastitis Agalactia syndrome), caused by bacterial strains susceptible to marbofloxacin.

CONTRA-INDICATIONS:
Do not use in cases where the pathogen involved is resistant to other fluoroquinolones (cross resistance).
Do not administer in animals with known hypersensitivity to the active substance or to any other quinolone or to any of the excipients.

DOSAGE AND MODE OF ADMINISTRATION:
Cattle:
Respiratory infections:
The recommended dosage is 8 mg marbofloxacin/kg body weight (2 ml product/25 kg body weight) in a single injection by intramuscular route. If the volume to be injected is more than 20 ml, it should be divided between two or more injection sites.
In cases of respiratory infections caused by Mycoplasma bovis, the recommended dose is 2 mg marbofloxacin/kg body weight (1 ml product/50 kg body weight), in a single daily injection for 3 to 5 consecutive days, by intramuscular or subcutaneous route.
The first injection may be given by the intravenous route.
Acute mastitis:
→ Intramuscular or subcutaneous use:
The recommended dosage is 2 mg marbofloxacin/kg body weight (1 ml/50 kg bodyweight) in a single daily injection, for 3 consecutive days. The first injection may also be given by the intravenous route.

Pigs (sows):

→ Intramuscular use:
The recommended dosage is 2 mg marbofloxacin/kg body weight (1 ml product/50 kg body weight) in a single daily injection, for 3 consecutive days.

To ensure administration of a correct dose, body weight should be determined as accurately as possible, to avoid underdosing.
In cattle and pig, the preferred injection site is the neck area.
The cap may be safely punctured up to 30 times. The user should choose the most appropriate vial size according to the target species to treat.

UNDESIRABLE EFFECTS

Transitory inflammatory lesions can occur at the injection site, without clinical impact, when administered via the intramuscular or subcutaneous route.
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.
However, in cattle, subcutaneous route was shown to be better tolerated locally than intramuscular route. Therefore, the subcutaneous route is recommended in heavy cattle.

SPECIAL PRECAUTIONS FOR USE AND WARNINGS:

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.
The efficacy data showed that the product has insufficient efficacy for the treatment of acute forms of mastitis induced by Gram-positive bacteria.

PACK SIZE:

Glass vials of 100 ml and 250 ml.