[Version 9,03/2022]

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

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

2. Composition

Each ml contains:

Active substance:
Marbofloxacin ..... 100.0 mg

Excipients:
Metacresol ..... 2.0 mg
Thioglycerol ..... 1.0 mg
Disodium edetate ..... 0.1 mg

Yellow greenish to yellow brownish, clear solution.

3. Target species

Cattle and pigs (sows and pigs for fattening).

4. Indications for use

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

Pigs:
- Treatment of Postpartum Dysgalactia Syndrome –PDS- (Metritis Mastitis Agalactia Syndrome), caused by bacterial strains susceptible to marbofloxacin.
- Treatment in pigs for fattening of respiratory tract infections caused by susceptible strains of *Actinobacillus pleuropneumoniae, Mycoplasma hyopneumoniae and Pasteurella multocida*.

5. Contraindications

Do not use in cases of hypersensitivity to the active substance, to any other quinolone or to any of the excipients.

6. Special warnings

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

Do not use in cases of resistance to other fluoroquinolones (cross-resistance).

Special precautions for safe use in the target species:

The use of the product should be based on identification and susceptibility testing of the target pathogen(s). If this is not possible, therapy should be based on epidemiological information and knowledge of susceptibility of the target pathogens at farm level, or at local/regional level.

Use of the product should be in accordance with official, national and regional antimicrobial policies.

An antibiotic with a lower risk of antimicrobial resistance selection (lower AMEG category) should be used for first line treatment where susceptibility testing suggests the likely efficacy of this approach.

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.

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 feeding of waste milk containing residues of marbofloxacin to calves should be avoided up to the end of the milk withdrawal period (except during the colostral phase), because it could select antimicrobial-resistant bacteria within the intestinal microbiota of the calf and increase the faecal shedding of these bacteria.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
People with known hypersensitivity to (fluoro)quinolones should avoid contact with the veterinary medicinal product. Care should be taken to avoid accidental self-injection as it can induce a slight irritation.
In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.
In case of contact with skin or eyes, rinse immediately with plenty of water.
Wash hands after use

Pregnancy and lactation:
Laboratory studies in rats and rabbits have not produced any evidence of teratogenic, foetotoxic or maternotoxic effects.
Safety of the veterinary medicinal product at 2 mg/kg body weight has been established in pregnant cows or in sucking calves and piglets when used in cows and sows. Can be used during pregnancy and lactation.
Safety of the veterinary medicinal product at 8 mg/kg body weight has not been established in pregnant cows or in sucking calves when used in cows. Therefore, this dose regimen should be used only according to the benefit/risk assessment by the responsible veterinarian.

Interaction with other medicinal products and other forms of interaction:
None known.

Overdose:
No clinical signs have been observed after administration of 3 times the recommended dose.
Signs such as acute neurological disorders may occur when the dose is exceeded. These signs should be treated symptomatically.
Do not exceed the recommended dose.

Special restrictions for use and special conditions for use:

ES: For administration only by a veterinarian (in case of intravenous route) or under their direct responsibility.

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

7. Adverse events

Cattle and pigs (sows and pigs for fattening)

Very rare(<1 animal / 10,000 animals treated, including isolated reports):
Application site disorders (e.g. injection site lesion, injection site swelling or injection site pain)

Transitory inflammatory lesions at the injection site can occur, when administered via the intramuscular or subcutaneous route. When administering by the intramuscular route which may persist for at least 18 days after injection.

In cattle, subcutaneous route was shown to be better tolerated locally than intramuscular route.

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system .

8. Dosage for each species, routes and method of administration

Cattle:
Respiratory infections:
The recommended dosage is 8 mg marbofloxacin/kg body weight (2 ml veterinary medicinal product/25 kg body weight) in a single injection by the 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 veterinary medicinal product/50 kg body weight), in a single daily injection for 3 to 5 consecutive days, by the intramuscular or subcutaneous route. The first injection may be given by the intravenous route.

Acute mastitis:
The recommended dosage is 2 mg marbofloxacin/kg body weight (1 ml veterinary medicinal product/50 kg body weight) in a single daily injection for 3 consecutive days by the intramuscular or subcutaneous route. The first injection may also be given by the intravenous route.

Pigs:
Treatment of Postpartum Dysgalactia Syndrome –PDS– (Metritis Mastitis Agalactia Syndrome):
The recommended dosage is 2 mg marbofloxacin/kg body weight (1 ml veterinary medicinal product/50 kg body weight) in a single daily injection for 3 consecutive days by the intramuscular route.

Treatment in pigs for fattening of respiratory infections:
The recommended dosage is 2 mg marbofloxacin/kg body weight (1 ml veterinary medicinal product/50 kg body weight) in a single daily injection for 3 to 5 consecutive days by the intramuscular route.

9. Advice on correct administration

To ensure administration of a correct dose, body weight should be determined as accurately as possible.
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.

10. Withdrawal periods

Cattle:

Indication	**Respiratory**		**Mastitis**
Dosage	2 mg/kg for 3 to 5 days (IV/IM/SC)	8 mg/kg on a single occasion (IM)	2mg/kg for 3 days (IV/IM/SC)
Meat and offal	6 days	3 days	6 days
Milk	36 hours	72 hours	36 hours

Pigs:
Meat and offal: 4 days.

11. Special storage precautions

Keep out of the sight and reach of children.

This veterinary medicinal product does not require any special storage conditions.
Do not use this veterinary medicinal product after the expiry date which is stated on the label after Exp. The expiry date refers to the last day of that month.

Shelf life after first opening the container: 28 days

12. Special precautions for disposal

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

Pack sizes:
Box with 1 glass vial of 50 ml
Box with 1 glass vial of 100 ml
Box with 1 glass vial of 250 ml
Box with 10 glass vials of 50 ml
Box with 10 glass vials of 100 ml
Box with 10 glass vials of 250 ml
Box with 1 PP vial of 100 ml
Box with 1 PP vial of 250 ml
Box with 10 PP vials of 100 ml
Box with 10 PP vials of 250 ml

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

DD/MM/YYYY

Detailed information on this veterinary medicinal product is available in the Union Product Database.

16. Contact details

Marketing authorisation holder and manufacturer responsible for batch release:

SP VETERINARIA S.A.
Ctra. Reus-Vinyols, km 4,1
43330 Riudoms (SPAIN)

Local representatives and contact details to report suspected adverse reactions:

España
{Nombre}
{Dirección}
ES-00000 {Ciudad}
Tel: + {Teléfono}
{E-mail}

Malta
{Isem}
{Indirizz}
MT-0000 {Belt/Raħal}
Tel: + {Numru tat-telefon}
{E-mail}

Polska
{Nazwa/ Nazwisko:}
{Adres:}
PL – 00 000{Miasto:}
Tel.: + {Numer telefonu:}
{E-mail}

Portugal
{Nome}
{Morada}
PT-0000–000 {Cidade}
Tel: + {Número de telefone}
{E-mail}

România
{Nume}
{Adresă}
{Oraş} {Cod poştal} – RO
Tel: + {Număr de telefon}
{E-mail}