

Consumer leaflet for a Veterinary Product

This medicine is marketed according to a veterinarian's prescription only.
For animal use only

1. NAME, FORM AND STRENGTH OF THE VETERINARY MEDICINE

MARBOCYL 2% SOLUTION FOR INJECTION VETERINARY

2. ACTIVE INGREDIENT AND ITS QUANTITY IN DOSE UNIT

One ml solution contains:

marbofloxacin 20 mg

Inactive ingredients: disodium edetate 0.1 mg/ml, thioglycerol 0.5 mg/ml, m-cresol 2 mg/ml. For a full list of excipients see section 13 below.

3. WHAT IS THE MEDICINE INTENDED FOR

In preruminant and ruminant calves:

- Treatment of respiratory infections caused by susceptible strains of *Pasteurella multocida*, *Mannheimia (Pasteurella) haemolytica* and *Mycoplasma bovis*.

In pigs:

- Treatment of respiratory infections caused by susceptible strains of *Actinobacillus pleuropneumoniae*, *Mycoplasma hyopneumoniae* and *Pasteurella multocida*.

The product should only be used when strain susceptibility has been tested.

Therapeutic group: fluoroquinolone antibiotics for systemic use.

4. CONTRAINDICATIONS

Do not administer in the event of bacteria resistant to other fluoroquinolones (cross-resistance).

Do not administer to an animal with known hypersensitivity to marbofloxacin or to another quinolone.

5. SIDE EFFECTS

Calves and pigs:

Side effects of undetermined frequency (frequency not established yet):	Injection site oedema ¹ ; injection site pain ² ; injection site lesion ^{2,3}
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¹ Transient reaction, in case of subcutaneous or intramuscular administration.

² In case of intramuscular administration.

³ Inflammatory lesions can last up to 6 days in pigs and 12 days in calves.

You can report side effects to the Ministry of Health by following the link 'Reporting Side Effects of Drug Treatment' on the Ministry of Health home page (www.health.gov.it) which links to an online form for reporting side effects. You can also use this link:

6. TARGET SPECIES

Cattle and pigs for fattening.

7. DOSAGE AND ADMINISTRATION

In preruminant and ruminant calves:

2 mg marbofloxacin per kg live weight, i.e. 1 ml of solution per 10 kg live weight in a daily subcutaneous or intramuscular injection for 3 to 5 days. The first injection can also be administered intravenously.

In pigs:

2 mg marbofloxacin per kg live weight, i.e. 1 ml of solution per 10 kg live weight in a daily intramuscular injection for 3 to 5 days.

8. HOW TO USE THE PRODUCT

Solution for injection. See section 7 for instructions.

9. WITHDRAWAL PERIOD

Meat and offal: In preruminant and ruminant calves: 6 days.
Pigs: 4 days.

Milk: the product should not be administered to animals producing milk for human consumption.

10. WARNINGS

- Special warnings for safe use in animals

Fluoroquinolones should only be used to treat clinical disorders not responding sufficiently to other antibiotic classes, or when it is expected they will not respond sufficiently to other antibiotic classes.

Whenever possible before using fluoroquinolones, perform bacterial susceptibility tests and consider official and local antibiotic use policies.

Off-label use of the product may increase the prevalence of fluoroquinolone-resistant bacteria and may reduce the efficacy of the treatment with other quinolones, given the risk of cross-resistance.

- Use in pregnant and lactating animals

Studies in laboratory animals (rats, rabbits) have shown no evidence of teratogenic, embryotoxic or maternotoxic effects from marbofloxacin.

Use of the product should be determined on the basis of the risk-benefit analysis as evaluated by the veterinarian.

If using in lactating cows, see the section 'Withdrawal period'.

- Interactions with other medicinal products and other forms of interactions

None known.

- Overdose

No sign of overdose has been observed after administration of 3 times the recommended dose of marbofloxacin.

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

- Incompatibilities

Do not mix this product with other medicinal products.

11. STORAGE INSTRUCTIONS

- Avoid poisoning! Keep this medicine and any other medicine in a closed place out of reach and sight of children and/or infants to avoid poisoning.
- Do not use this medicine after the expiry date (exp. date) which is stated on the package. The expiry date refers to the last day of that month.
- Storage conditions: Store at a temperature below 25°C.
Use this product within 28 days of first opening.

12. INSTRUCTIONS FOR DISPOSING OF THE PRODUCT/REMAINING PRODUCT AT THE END OF USE

Dispose of any remaining veterinary medicine or waste obtained from using a veterinary medicine in the same manner as toxic waste; do not discard into a sewer.

13. ADDITIONAL INFORMATION

In addition to the active ingredient, the medicine also contains:

Mannitol, gluconolactone, m-cresol, thioglycerol, disodium edetate, water for injection

What does the medicine look like and what is the content of the package:

Yellow green to yellow brown aqueous solution, in a 100 ml amber glass vial, with a rubber stopper.

Registration holder: Eliezer Linevitz Ltd., 6 Adom St., P.O.B 7006, Kanot Industrial Aera.

Manufacturer: Vetoquinol, BP 189, 70204 Lure Cedex, France

Revised in November 2025.

Registration number of this medicine in the Ministry of Health National Drug Registry: 083-94-92387-00