SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

MARBOCYL 2% SOLUTION FOR INJECTION VETERINARY

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:

Marbofloxacin……. 20.0 mg

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Mannitol	
Gluconolactone	
m-cresol	2.0 mg
Thioglycerol	0.5 mg
Disodium edetate	0.1 mg
Water for injection	

Solution for injection.

Yellow-greenish to yellow brownish aqueous solution.

3. CLINICAL INFORMATION

3.1. Target species

Bovines and porcines during fattening.

3.2. Indications for use for each of the target species

In pre-ruminant 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.

3.3. Contraindications

Bacterial infections with resistance to other fluoroquinolones (cross-resistance).

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

3.4. Special warnings for each target species

None.

3.5. Special precautions for use

Special precautions for use in animals

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. Official and local antimicrobial policies should be taken into account when the veterinary medicinal product is used.
Use of the veterinary medicinal 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 animals

None.

Other precautions

None.

3.6. Adverse events

Calves and pigs:

Undetermined frequency (cannot be estimated from the available data):	Injection site œdema[1]; injection site pain[2]; injection site lesion[2,3]

[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.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Any suspected adverse events should be reported to the Ministry of Health according to the National Regulation by using an online form
https://sideeffects.health.gov.il

3.7. Use during pregnancy, lactation or lay

Pregnancy and lactation:
Laboratory studies in rats and rabbits have not produced any evidence of teratogenic, embryotoxic or maternotoxic effects.
Use only according to the benefit-risk assessment by the responsible veterinarian.
See also paragraph 3.12.

3.8. Interaction with other medicinal products and other forms of interaction

Unknown.

3.9. Administration routs and dosage

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

3.10. Symptoms of overdose (and where applicable, emergency procedures and antidotes)

No sign of overdosage has been observed with marbofloxacin after administration of 3 times the recommended dose.
overdosage may cause signs in the form of acute neurological disorders which would have to be treated symptomatically.

3.11. Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

For administration only by a veterinarian

3.12. Withdrawal periods

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.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code:

QJ01MA93.

4.2 Pharmacodynamics

Marbofloxacin is a synthetic, bactericidal antimicrobial, belonging to the fluoroquinolone group which acts by inhibition of DNA gyrase. It is effective against a wide range of Gram positive bacteria (in particular *Staphylococci),* and Gram negative bacteria *(Escherichia coli, Pasteurella multocida, Pasteurella haemolytica* and *Actinobacillus pleuropneumoniae)* as well as *Mycoplasma (Mycoplasma bovis, Mycoplasma hyopneumoniae).*
Resistance to *Streptococcus* may occur.

4.3 Pharmacokinetics

After subcutaneous or intramuscular administration in cattle and pigs at the recommended dose of 2 mg/kg, marbofloxacin is readily absorbed and reaches maximal plasma concentrations of 1.5 µg/ml within less than 1 hour.
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, uterus) it achieves higher concentrations than in plasma.
Marbofloxacin is eliminated slowly in preruminant calves ($t_{1/2}$ = 5-9 hours) and pigs ($t_{1/2}$= 8-10

hours), faster in ruminant cattle ($t_{1/2}$ = 4-7 hours) predominantly in the active form in urine and faeces.

5 PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Do not mix with any other veterinary medicinal product for use with the veterinary medicinal product.

5.2 Shelf life

The expiry date of the product is indicated on the packaging materials. Shelf life after first opening the primary packaging: 28 days.

5.3 Special precautions for storage

Store below 25°C.

5.4 Nature and composition of immediate packaging

Type II amber glass vial, rubber stopper.

Presentation

Box of one vial of 100 ml.

5.5 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

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 national collection systems applicable to the veterinary medicinal product concerned.

6 MANUFACTURER

Vetoquinol, BP 189,70204 Lure Cedex, France

7 NAME OF THE MARKETING AUTHORISATION HOLDER

Eliezer Linevitz Ltd.
Kanot Industrial Area, Adom 6 St., P.O.B 7006.

8 MARKETING AUTHORISATION NUMBER

083-94-92387-00

Revised in November 2025.