This leaflet format has been determined by the Ministry of Health and the content has been checked and approved in 1.2020

SUMMARY OF PRODUCT CHARACTERISTICS

1. Name of the veterinary medicinal product

MARBOCYL 10% SOLUTION FOR INJECTION VETERINARY

2. Qualitative and quantitative composition

One ml contains:

Active substance(s):

Marbofloxacin……. 100.0 mg

Excipient(s):

Disodium edetate……. 0.1 mg

Thioglycerol…….... 1.0 mg

m-cresol ..... 2.0 mg

For a full list of excipients, see section 'List of excipients'.

3. Pharmaceutical form

Solution for injection.
For IM, IV or SC injection.

4. Clinical particulars

4.1. Target species

Cattle and sows

4.2. Indications for use, specifying the target species

IN CATTLE:

Treatment of respiratory infections with susceptible strains of Pasteurella multocida, Mannheimia (Pasteurella) haemolytica and Mycoplasma bovis.
Treatment of acute Escherichia coli mastitis susceptible to marbofloxacin during the lactation period.

IN SOWS:

Treatment of Metritis-Mastitis-Agalactic Syndrome with bacterial strains sensitive to marbofloxacin.

4.3. 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.

4.4. Special warnings for each target species

None.

4.5. Special precautions for use

i) 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 product is used.
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.
Efficacy data have shown an insufficient efficacy of the product for the treatment of acute mastitis caused by Gram positive strains.

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

None.

iii) Other precautions

None.

4.6. Adverse reactions (frequency and seriousness)

Administration by the intramuscular route may cause transient local reactions such as pain and swelling at the injection site and inflammatory lesions which persist 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 adult cattle. For the injections, the neck should be preferred in cattle and pigs.
No other undesirable effects have been observed in cattle and pigs.

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

4.7. Use during pregnancy, lactation or lay

Studies in laboratory animals (rats, rabbits) did not show any teratogenic, embryotoxic effects or any maternal toxicity 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 cows during gestation or in suckling calves when used in cows. Use only according to the benefit/risk assessment by the veterinarian.

In the case of use in the cow during lactation, see paragraph «Withdrawal Period».

4.8. Interactions with other medicinal products and other forms of interaction

None known.

4.9. Posology and route of administration

IN CATTLE:
Treatment of respiratory infections caused by sensitive strains of *Pasteurella multocida, Mannheimia haemolytica*: the recommended dosage is 8 mg/kg (2 mL/25kg bw) in a single injection by intramuscular route.

Treatment of respiratory infections caused by sensitive strains of *Mycoplasma bovis*: the recommended dose is 2 mg/kg (1 mL/50 kg bw) in a single daily injection by subcutaneous or intramuscular route, for 3 to 5 consecutive days. The first injection may be given by the intravenous route.

Treatment of acute mastitis: 2 mg/kg (1 mL/50 kg bw) in a single daily injection by subcutaneous or intramuscular route, for 3 consecutive days.
The first injection may also be given by the intravenous route.

IN SOWS:
The recommended dosage is 2 mg/kg (1 mL/50 kg bw) in a single daily injection by the intramuscular route, for 3 days.

4.10. Overdose (symptoms, emergency procedures, antidotes), if necessary

No sign of overdosage has been observed 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.

4.11. Withdrawal period

Cattle	Indication	Respiratory infection		Mastitis
	Dosage	2 mg/kg for 3 to 5 days (IV/IM/SC)	8 mg/kg in a single injection (IM)	2 mg/kg for 3 days (IV/IM/SC)
	Meat and offals	6 days	3 days	6 days
	Milk	36 hours	72 hours	36 hours
Sows	Meat and offals	4 days		

5. Pharmacological properties

Pharmacotherapeutic group: fluoroquinolone.
ATC-vet code: QJ01MA93.

5.1. Pharmacodynamic properties

Marbofloxacin is a synthetic, bactericidal antimicrobial, belonging to the fluoroquinolone group. It acts by inhibition of DNA gyrase. Its spectrum of action *in vitro* is broad, targeted against Gram positive bacteria (especially *Staphylococcus),* Gram negative bacteria *(Escherichia coli, Pasteurella multocida)* and mycoplasma *(Mycoplasma bovis)*
Resistance to *Streptococcus* may be encountered.

5.2. Pharmacokinetic characteristics

After subcutaneous or intramuscular administration in cattle and pigs at the recommended dose of 2mg/kg, marbofloxacin is readily absorbed and reaches maximal plasma concentrations of around 1.5µg/ml within less than one hour.
Its bioavailability is close to 100%.
Marbofloxacin is weakly bound to plasma proteins (less than 10% in pigs and 30% in cattle), and is extensively distributed in the body. In most tissue (liver, kidney, skin, lung, uterus) it achieves a higher concentration than in plasma.
After intramuscular administration in dairy cows, Marbofloxacin reaches a maximal milk concentration of 1,02 µg/ml (C_{max} after first administration) at 2,5 hours (T_{max} after first administration).

Marbofloxacin is eliminated slowly in preruminant calves ($t_{1/2}$ = 5-9 hours) and pigs ($t_{1/2}$= 8-10 hours), more rapidly in ruminant cattle ($t_{1/2}$ = 4-7 hours) and mainly in active form in the urine and faeces.

After single intramuscular administration in cattle at the recommended dose of 8 mg/kg, Marbofloxacin reaches a maximal plasma concentration (C_{max}) of 7,3 µg/ml at 0,78 hour (T_{max}). It is bound to plasma proteins around 30%.

Marbofloxacin is eliminated slowly ($t_{1/2}$ = 15,60 hours), and mainly in active form in the urine and faeces.

6. Pharmaceutical information

6.1. List of excipients

Disodium edetate
Thioglycerol
m-cresol
Gluconolactone
Water for injection

6.2. Major incompatibilities

Non known.

6.3. Shelf life

The expiry date of the product is indicated on the packaging materials.

Shelf life after first opening the primary packaging: 28 days.

6.4. Special precautions for storage

Following withdrawal of the first dose, do not store above 25°C.

Protect from light.

6.5. Nature and composition of immediate packaging

Type II amber glass vial
Chlorobutyl stopper
Box of one 50 ml vial
Box of one 100 ml vial
Box of one 250 ml vial

Not all pack sizes may be marketed.

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

The empty packaging and any remaining product should be disposed of in accordance with current practices governed by regulations on waste materials.

7. Manufacturer

VETOQUINOL

MAGNY VERNOIS
70200 LURE

FRANCE

8. Registration holder

LINEVITZ ELIEZER

25 HAELA ST., EVEN-YEHUDA 40500

9. Registration number(s)

141-22-92277