SUMMARY OF PRODUCT CHARACTERISTICS

1. Name of the veterinary medicinal product

MARBOCYL 2% SOLUTION FOR INJECTION VETERINARY

2. Qualitative and quantitative composition

One ml contains:

Active substance(s):

Marbofloxacin……. 20.0 mg

Excipient(s):

Disodium edetate……. 0.1 mg

Thioglycerol……..... 0.5 mg

m-cresol ..... 2.0 mg

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

3. Pharmaceutical form

Solution for injection.
Yellow green to yellow brown aqueous solution.

4. Clinical particulars

4.1. Target species

Bovines and porcines during fatting.

4.2. Indications for use, specifying 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.

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 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.
Bacterial sensitivity tests to antibiotics should be carried out before using fluoroquinolones whenever possible, and should take account of 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.

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

None.

iii) Other precautions

None.

4.6. Side effects (frequency and severity)

Administration by subcutaneous and intramuscular route may cause temporary swelling.
Administration by intramuscular route may cause pain and inflammatory lesions at the injection site. Inflammatory lesions can last for 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/

4.7. Use during pregnancy, lactation or lay

Studies on 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.
See section 'Withdrawal period'.

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

None known.

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

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

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.

4.11. 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.

5. Pharmacological properties

Pharmacotherapeutic group: anti-infective for systemic use (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 is broad, targeted against Gram positive bacteria (especially *Staphylococcus),* Gram negative bacteria *(Escherichia coli, Pasteurella multocida, Mannheimia (Pasteurella) haemolytica* and *Actinobacillus pleuropneumoniae)* and mycoplasma *(Mycoplasma bovis* and *Mycoplasma hyopneumoniae).*
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 peak 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.

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.

6. Pharmaceutical information

6.1. List of excipients

Disodium edetate
Thioglycerol
m-cresol
Gluconolactone
Mannitol
Water for injection

6.2. Major incompatibilities

Do not mix this product with other medicinal products.

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

Store below 25^0C.

6.5. Nature and composition of immediate packaging

Type II amber glass vial
rubber stopper

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
70204 LURE CEDEX
FRANCE

8. Registration holder

LINEVITZ ELIEZER LTD.

KANOT INDESTRIAL AERA, ADOM 6 ST., P.O.B 7006.

9. Registration number(s)

083-94-92387-00

Box of one 100 ml vial.

Approved in July 2020.