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

ARISTOS 2 VETERINARY, SOLUTION FOR INJECTION

2. **ACTIVE INGREDIENT** and its quantity in a dose unit

One ml solution contains:

Marbofloxacin 20 mg

Inactive excipients: Disodium edetate 0.1 mg/ml, Thioglycerol 0.5 mg/ml, Metacresol 2 mg/ml. For a full list of excipients see section 13 below.

3. WHAT IS THE MEDICINE INTENDED FOR

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.

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

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.
Side effects can be reported to the Ministry of Health by clicking on the link "Adverse Drug Reactions Report" that appears on the home page of the Ministry of Health web site (www.health.gov.il), which leads to an online form for reporting side effects. Alternatively you can use the following link: https://sideeffects.health.gov.il

6. TARGET SPECIES

Bovines and porcines during fatting.

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 and per day, 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.
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.

- Use during pregnancy or lactation of the treated animal

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'.

- Interaction with other medicinal products and other forms of interaction

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 drug 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 shown on the package. The expiry date refers to the last day of the month indicated.
- Storage conditions: Store at a temperature below 25^0 C.
  after first opening, the product may be used for 28 days.

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

Any unused veterinary medicinal product or waste materials derived from veterinary medicinal product use, should be disposed of as toxic waste. Do not throw into the sewage system.

13. ADDITIONAL INFORMATION

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

Mannitol, Gluconolactone, Metacresol, Thioglycerol, Disodium edetate, Water for injection

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

100 ml, 250 ml or 500 ml clear yellow solution, in an amber glass bottle with a rubber stopper, packed in a cardboard box. Not all pack sizes may be marketed.

Manufacturer: FATRO S.P.A., VIA EMILIA 285 - 40064 ,OZZANO EMILIA, BOLOGNA, ITALY

Registration holder: Romat Ltd., Ha'maapilim 39/104, Herzliya

Revised in October 2020.

Registration number of this medicine in the Ministry of Health State Medicine Registry: 165-04-35517-00