Consumer Leaflet for a Veterinary Product

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

1. Name of the veterinary medicine, form and strength

ARISTOS 10 VETERINARY, SOLUTION FOR INJECTION

2. Active ingredient and quantity in a single dose:

Marbofloxacin 100 mg/ml

Excipients – each ml contains**:**

Metacresol (2 mg), Thioglycerol (1 mg), Disodium edetate (0.1 mg)
For a full list of excipients, see section 13: "additional information".

3. What is the medicine intended for

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.

Therapeutic group: fluoroquinolone.

4. Contra-indications

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 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.

Side effects can be reported to the Ministry of Health by clicking on the link "Adverse Drug Reactions Repot" 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 animals: Cattle and sows.

7. Dosage and 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 body weight) 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 body weight) 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 body weight) 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 body weight) in a single daily injection by the intramuscular route, for 3 days.

8. How to use the product

For intravenous, intramuscular or subcutaneous administration.

9. Withdrawal period

	Indication	**Respiratory Infection**		**Mastitis**
Cattle	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		

10. Warnings

- Special warnings for use of the medicine in target 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. Use of the product deviating from the instructions given in the leaflet 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.

- Pregnancy and lactation in target animals

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».

- Interaction with other medicinal products and other forms of interaction

None known.

- Overdose

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.

11. Storage instructions

- Avoid poisoning! This medicine, and any other medicine, must be kept in a closed place out of the reach of children and/or infants to prevent accidental poisoning.
- Do not use the medicine after its expiration date (exp. date) as it appears on the package. The expiration date refers to the last day of the stated month.
- Storage conditions: Store below 25°C.
- after first opening the packaging, use within 28 days.

12. Instructions for disposing of the product / remaining product at the end of its use

Any unused veterinary medical product or any substance remaining after using the veterinary medical product must be disposed of as toxic waste; do not throw into the sewage system.

13. Additional information

- in addition to the active ingredient, This medicine also contains: Gluconolactone, Metacresol, Thioglycerol, Disodium edetate, Water for injection
- How 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 carton box. Not all pack sizes may be marketed.

- **Registration holder name and address:** Romat Ltd., Ha'maapilim 39/104, Herzliya
- **Manufacturer name and address**: FATRO S.P.A., VIA EMILIA 285 - 40064 ,OZZANO EMILIA, BOLOGNA, ITALY

Revised in October 2020.

Registration number of this medicine in the Ministry of Health State Medicine