

Patient Leaflet for Veterinary Product

This Medicine is marketed with a Veterinarian Prescription only

For use in Animals only

1. Name, form and strength of the Medicine

Vetamar 100 mg/ml Veterinary, 100 mg/ml Solution for Injection

2. Composition

Active Ingredient:

Each ml of the solution contains: Marbofloxacin 100 mg

For the list of inactive ingredients, see Section 13.

3. What is the Medicine intended for?

For Cattle: For the treatment of inflammations in the respiratory system caused by organisms susceptible to Marbofloxacin. Treatment should only be given after establishing the susceptibility of the bacteria to the medicinal substance and when no alternative treatment exists (due to established resistance to other medicinal substances).

For Pigs: For the treatment of Metritis Mastitis Agalactia syndrome, caused by organisms susceptible to Marbofloxacin. Treatment should only be given after establishing the susceptibility of the bacteria to the medicinal substance and when no alternative treatment exists (due to established resistance to other medicinal substances).

Therapeutic group: Marboflaxacin is an antibiotic of the fluoroquinolones family.

4. Contraindications

None.

5. Side effects:

There are no expected severe side effects in dosages of up to 3 or 5 times the recommended dosage in cattle and pigs, respectively.

In particular, no lesions have been observed in the articular joints.

Intramuscular or subcutaneous injections are well tolerated although transient inflammatory lesions may be caused in the injection area, without a clinical effect.

Side effects can be reported to the Ministry of Health by clicking on the link found on the home page of the Ministry of "Report Side Effects of Drug Treatment" Health website (www.health.gov.il) which directs to the online form for reporting side effects or via the following link:

<https://sideeffects.health.gov.il>

6. Target animals:

For use in cattle: I.V. / S.C. / I.M.

For use in pigs: I.M.

7. Route of Administration and Dosage:

The recommended dosage is 2 mg/kg body weight /day (1 ml for 50 kg body weight) in a single daily injection.

For cattle: Intramuscular injection, subcutaneous or intravenous once a day for 3-5 days.

For pigs: Intramuscular injection once a day for 3 days.

8. Withdrawal period:

Cattle:

Withdrawal period for meat: 6 days

Withdrawal period for milk: 36 hours

Pigs:

Withdrawal period for meat: 4 days.

9. Warnings

Using this medicine in a way that does not correspond to the instructions in this leaflet may increase the prevalence of bacterial resistance to fluoroquinolones and decrease the effectiveness of the treatment of other quinolones, due to the potential of cross-resistance.

Warnings for the caregiver:

People with known hypersensitivity to fluoroquinolones should avoid using this product.

Wash your hands after use.

Pregnancy and breastfeeding: Vetamar 100 mg/ml Veterinary can be given to pregnant and lactating cattle and pigs.

Reactions with other medicines, and other types of reactions: None.

Overdose: Overdose may cause acute signs in the form of neurological disorders which would have to be treated symptomatically.

Incompatibility: None.

10. Storage Instructions

- Avoid poisoning! This medicine, and all other medicines, must be stored in a closed place out of the reach and sight of children and/or infants, to avoid poisoning.
- Do not use the medicine after the expiry date (Exp. Date) stated on the package. The expiry date refers to the last day of that month.
- Store below a temperature of 25°C. Keep in the original package in order to protect from light.
- Use the bottle within 28 days after first opening, afterwards dispose of any unused material.

11. Instructions regarding the disposal of the product/leftovers of the product after use

Manure and slurry containing Marbofloxacin leftovers should not be spread on the same area of land in successive years.

Any unused veterinary medicinal product or waste materials derived from veterinary medicinal product should be disposed of as toxic waste; do not discard into wastewater.

12. Additional Information

- **In addition to the active ingredient this medicine contains:**
Gluconolactone, metacresol, thioglycerol, disodium edetate, water for injections.
- **What this medicine looks like and contents of the package:**
Vetamar 100 mg/ml Veterinary is a yellow or greenish-yellow to brown transparent solution packed in a vial. Each package contains 1 or 10 vials of 100 ml each. Not all pack sizes may be marketed.
- **Registration holder:**
VETMARKET LTD., 23 HACHORESH WAY, INDUSTRIAL PARK MODI'IN
REGION
- **Manufacturer name:**
Vet-Agro Multi-Trade Company Sp. z o.o., Lublin, Poland.

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Drug Registration Number at the Israel Drug Registry of the Ministry of Health:161-47-35195