

## **Veterinary medicine package leaflet**

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

### **1. NAME OF THE VETERINARY MEDICINE, FORM AND STRENGTH**

Forcyl 160 mg/mL solution for injection for cattle veterinary

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

Marbofloxacin 160 mg/mL

**Inactive excipients** - Each mL contains:

Benzyl alcohol 15 mg

For the full list of inactive ingredients, see Section 13: " Additional information."

### **3. WHAT IS THE MEDICINE INTENDED FOR**

**In cattle:**

- Treatment of respiratory infections caused by sensitive strains of *Pasteurella multocida* and *Mannheimia haemolytica*.

**In lactating cows:**

- Treatment of acute mastitis caused by strains of *Escherichia coli* sensitive to Marbofloxacin

Therapeutic group: Antibiotics in the fluoroquinolone class

### **4. CONTRAINDICATIONS**

Do not use in cases of hypersensitivity to the active ingredient, to any other fluoroquinolones or to any of the product inactive ingredients.

Do not use in cases where the infecting pathogen is resistant to other fluoroquinolones (cross resistance).

### **5. SIDE EFFECTS**

Very rare side effects (may occur in less than 1 in 10,000 treated animals, including individual reports)
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Injection site reactions (such as pain, swelling) <sup>1</sup>
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Arthritis (arthropathy) <sup>2</sup> Severe allergic reaction (anaphylactic reaction) <sup>3</sup>
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<sup>1</sup>A transient reaction in the cases of an intramuscular injection. May persist for up to 7 days after injection.

<sup>2</sup>In cattle, such lesions were observed after three-day treatment. These lesions did not induce clinical signs and should be reversible, particularly if they appear after a single administration.

<sup>3</sup>May be life-threatening.

Side effects can be reported to the Ministry of Health by clicking on the link "Reporting Side Effects of Drug Treatment" that appears on the home page of the Ministry of Health website ([www.health.gov.il](http://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: Cattle

## 7. DOSAGE AND ADMINISTRATION ROUTE

To ensure a correct dosage, bodyweight should be determined as accurately as possible to avoid underdosing.

Where there is slight cloudiness or visible particles present, such cloudiness or particles disappear when the bottle is shaken before use.

**Treatment of respiratory infections:** 10 mg/kg body weight (10 mL /160 kg body weight) in a single intramuscular injection.

**Treatment of acute mastitis caused by sensitive strains of *Escherichia coli*:** 10 mg/kg body weight (10 mL/160 kg body weight) in a single intramuscular or intravenous injection.

If the volume to be injected intramuscularly is more than 20 mL, it should be divided between two or more injection sites.

## 8. HOW TO USE THE PRODUCT

For intravenous or intramuscular injection.

## 9. WITHDRAWAL PERIOD

Meat and offal: 5 days

Milk: 48 hours

## 10. WARNINGS

### Special warnings

The efficacy of the veterinary product has not been tested for mastitis caused by Gram-positive bacteria.

### Special warnings for safe use in target animals

When this veterinary product is used, official and local antimicrobial policies must be considered.

Fluoroquinolones should be reserved for the treatment of clinical conditions which have not responded well, or are not expected to respond well, to other classes of antimicrobials.

To the extent possible, use of this veterinary product should only be based on susceptibility testing.

### Special precautions regarding human safety of the person administering the product

- People with known hypersensitivity to (fluoro)quinolones should avoid contact with this veterinary product.
- In case of contact with skin or eyes, rinse with plenty of water. Care should be taken to avoid accidental self-injection.
- Accidental self-injection can induce a slight irritation.
- In case of accidental self-injection, seek medical advice immediately and show the label or the package leaflet to the physician.
- Wash hands after use.

### Pregnancy and lactation of the treated animal

Use only according to the benefit/risk assessment by the responsible veterinarian. Safety of the product at a dosage of 10 mg/kg has not been determined in pregnant cows or in suckling calves when used in cows. Studies in laboratory animals (rats, rabbits) did not show any evidence of a teratogenic, embryotoxic or maternotoxic effects associated with the use of marbofloxacin.

### Interactions with other medicinal products and other forms of interactions

None known

### Overdose

Lesions of the joint cartilage were observed in some animals treated at 10 mg/kg or 30 mg/kg for three times the recommended treatment duration, but did not induce clinical signs. Moreover, no other signs of overdose were observed throughout this study.

Overdose may cause signs such as acute neurological disorders which should be treated symptomatically.

### Incompatibility

In the absence of compatibility tests, this veterinary product should not be mixed with other veterinary products.

## **11. STORAGE INSTRUCTIONS**

- Avoid poisoning! Keep this medicine and any other medicine 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 (exp. date) shown on the package. The expiry date refers to the last day of the month indicated.
- Storage conditions: Store below 25°C.
- After first opening, the product may be used for 28 days at a temperature below 25°C.

## **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 ingredients, this medicine also contains:**  
Glucono-delta-lactone, benzyl alcohol, water for injection.
- **What the medicine looks like and contents of the pack:**  
Clear solution of yellow-greenish to yellow-brown color in an amber-colored vial with the volume of 50 mL, 100 mL or 250 mL with a rubber stopper, packaged in a carton box. Not all package sizes may be marketed.
- **Registration holder's name and address:** Eliezer Linevitz Ltd., 6 Adom St., P.O. Box 7006, Kannot Industrial Area
- **Manufacturer's name and address:** Vetoquinol S.A, Magny Vernois, 70200 Lure, France

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**Registration number of the medicine in the Ministry of Health's National Drug Registry: 151-94-33855**