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

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 excipients, see Section 13: " Additional information."

3. WHAT IS THE MEDICINE INTENDED FOR

In cattle: Therapeutic treatment of respiratory infections in cattle 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: Fluoroquinolone

4. CONTRAINDICATIONS

Do not use in animals with known hypersensitivity to the active ingredient, to any other fluoroquinolones or to any of the product inactive excipients.
Do not use in cases where the pathogen involved is resistant to other fluoroquinolones (cross resistance).

5. SIDE EFFECTS

In very rare cases (may occur in less than 1 of 10,000 treated animals), administration by the intramuscular route may cause transient local reactions such as pain and swelling at the injection site which may persist up to 7 days after injection.
Fluoroquinolones are known to induce arthropathies. In cattle, such lesions were observed after a three days treatment with the 16% marbofloxacin

solution. These lesions did not induce clinical signs and should be reversible, particularly if they were to be observed after a single administration.
In very rare cases (may occur in less than 1 of 10,000 treated animals), anaphylactic-type (allergic) reactions with a potentially fatal outcome might occur.

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

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 i.e. 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 i.e. 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 for safe use in target animals

Official and local antimicrobial policies should be taken into account when this product is used.
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. Wherever possible, use of the product should only be based on susceptibility testing.
Use of the product deviating from the instructions given in this 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.
The efficacy of the product has not been tested for the treatment of acute mastitis caused by Gram positive bacterial strains.

Special precautions regarding human safety of persons administering the medicinal product

•People with known hypersensitivity to (fluoro)quinolones should avoid using this 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 or lactation of the treated animal

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

Interaction with other medicinal products and other forms of interaction

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 overdosage was observed throughout this study.
Overdosage 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 shown on the package. The expiry date refers to the last day of the month indicated.
- Storage conditions: Store below 25^0C.
- 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 substances, the medicine includes also: Glucono-delta-lactone, Benzyl alcohol, Water for injection.
- Appearance and package contents – 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 available.
- **Registration holder**: Eliezer Leibovitz, 6 Edom St., P.O. Box 7006, Kannot Industrial Area
- **Manufacturer's name and address:** Vetoquinol, Magny Vernois, 70200 Lure, France

Approved in 03/2021

Registration number of this medicine in the Ministry of Health State Medicine Registry: 151-94-33855