This leaflet has been reviewed and approved 9/2017

SUMMARY OF PRODUCT CHARACTERISTICS
Veterinary use only - Prescription only medicine

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Marbonor 100 mg/ml Veterinary Solution for injection
I.M, I.V, S.C injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:
Active Substance:
Marbofloxacin 100 mg
For a full list of excipients, see section 13 “further information”

3. Indications for use

Cattle
Treatment of respiratory infections caused by sensitive strains of *Pasteurella multocida, Psteurella heamolytica bovis.*
Sows
Treatment of Metritis Mastitis Agalactia Syndrome (postpartum dysgalactia syndrome, PDS) caused by bacterial strains sensitive to marbofloxacin
Treatment in both species should be given only after the sensitivity of the bacteria has been proven and it has been found that there is no alternative treatment (proven resistance to other agents).
Pharmacotherapeutic Group: Antibacterials, Flouroquinolones

4. Contraindications

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

5. Adverse reactions (frequency and seriousness)

Administration by the intramuscular route may cause transient local reactions such as pain and swelling at the injection site and inflammatory lesions which may persist for at least 12 days after injection.
In cattle subcutaneous route was shown to be better tolerated locally than intramuscular route. Therefore, the subcutaneous route is recommended in heavy cattle.
Side effects can be reported to the Ministry of Health by clicking on the link "Reporting adverse events due to drug treatment" found on the home page of the Ministry of Health website (www.health.gov.il) which refers to the online form for reporting adverse events, or by entering the link:
https://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffectMedic@moh.gov.il

6. Target Species:

Cattle, sows

7. Amounts to be administered and administration route

ro ensure administration of a correct dose, bodyweight should be determined as accurately as possible to avoid underdosing.
The recommended dosage is 2 mg/kg/day (1 ml/50kg/day).

Cattle: one injection per day for 3 to 5 days given by intramuscular, subcutaneous or intravenous routes.
Pigs: one injection per day for 3 days, given by intramuscular route.
For the injections, the neck should be preferred in cattle and pigs

8. How to use the preparation:
The product is injected by intramuscular, subcutaneous or intravenous routes in cattle and by intramuscular route in pigs.
The vial may be broached up to 35 times. The user should choose the most appropriate vial size according to the target species to be treated.

9. Withdrawal period
Cattle: Meat: 6 days.
Milk: 36 hours.
Pigs: Meat: 4 days.

10. Special warnings and precautions for use:

- Special precautions for use in animals:
- Official and local antimicrobial policies should be taken into account when the 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. Fluoroquinolones should only be used based upon susceptibility testing. Use of the product deviating from the instructions given in the leaflet may increase the prevalence of bacteria resistant the fluoroquinolones and may decrease the effectiveness of treatment with other quinolones due to the potential for cross resistance.
- Special precautions to be taken by the person administering the veterinary medicinal product to animals:
- People with known hypersensitivity to (fluoro)quinolones should avoid any contact with the veterinary medicinal product.
- If the product comes into contact with skin or eyes, rinse with copious amounts of water.
- Do not drink, eat or smoke whilst using the veterinary medicinal product.
- Wash hands after use.
- Accidental self-injection can induce a slight irritation
  In case of accidental self-injection or ingestion, seek medical advice immediately and show package \eaflet or the label to the physician
- Interaction with other medicinal products and other forms of interaction:
  None known
- Use during pregnancy, lactation or lay
  May be used in pregnant and lactating cows and sows.
- Overdose:
  No severe side-effects are to be expected at doses up to 3 or 5 times the recommended dose in cattle and pigs respectively.
  Signs such as neurological disorders may occur when the dose is exceeded. Such signs should be treated symptomatically

11. Storage instructions

- Prevent poisoning! This medicine and any other medicine should be kept in a safe place out of the reach of children and / or infants and thereby prevent poisoning.
- Do not use this medicine after the exp date on the package. The expiration date refers to the last day of that month.
- Storage conditions: Do not store above 25^{o}c. protect from light.
- Shelf-life after fırst opening the immediate packaging: 28 days. Remedies should be destroyed

after 28 days.

12. Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products:
Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed as toxic waste. Do not dispose of sewage.

13. FURTHER INFORMATION:
In addition to the active ingredient the product also contains:
Gluconolactone; Monothioglycerol; Metacresol; Disodium Edetate; Water for injections
Pharmaceutical form:

- Clear yellow to amber solution

Packaging sizes:
Glass vials contains 20,50,100,250 and 500 ml
Not all pack sizes may be marketed.
Registration holder: Comex Ltd. HABNAYAH ST. 12, INDUSTRIAL AREA HAR TOV "A" , BET SHEMESH
Manufacturer: Norbrook Laboratories Limited , Station Works, Newry, BT35 6JP, Northern Ireland, UK
Product registration number: 159-23-34705-00