B. PACKAGE LEAFLET

PACKAGE LEAFLET:

Greece, Austria, Belgium, Bulgaria, Czech Republic, the Netherlands, Poland	MARBOVET 100mg/ml solution for injection for cattle and pigs.
Spain, Portugal, Romania	MARVETIN 100mg/ml solution for injection for cattle and pigs.

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder and manufacturer responsible for batch release:

Vet-Agro Multi-Trade Company sp. z o.o.
Gliniana str.32
20-616-Lublin
Poland
Tel. + 48 81 4452300
Fax. +48 81 4452320
E-mail: vet-agro@vet-agro.pl

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Greece, Austria, Belgium, Bulgaria, Czech Republic, the Netherlands, Poland	MARBOVET 100 mg/ml solution for injection for cattle and pigs.
Spain, Portugal, Romania	MARVETIN 100 mg/ml solution for injection for cattle and pigs.

Marbofloxacin

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

Each ml contains:

Active substance :
Marbofloxacin ..... 100.0 mg

Excipients :
Metacresol ..... 2.0 mg
Thioglycerol ..... 1.0 mg
Disodium edetate..... 0.1 mg

Yellow greenish to yellow brownish, clear solution.

4. INDICATION(S)

Cattle:
Treatment of respiratory infections caused by strains of Pasteurella multocida, Mannheimia haemolytica, Mycoplasma bovis and Histophilus somni susceptible to marbofloxacin.

Treatment of acute mastitis caused by strains of *Escherichia coli* susceptible to marbofloxacin during the lactation period.

Pigs (sows):
Treatment of Postpartum Dysgalactia Syndrome - (PDS) – (Metritis Mastitis Agalactia Syndrome) caused by bacterial strains susceptible to marbofloxacin.

5. CONTRAINDICATIONS

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

6. ADVERSE REACTIONS

Transitory inflammatory lesions can occur at the injection site, without clinical impact, when administered via the intramuscular or subcutaneous route.

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.

However, in cattle, subcutaneous route was shown to be better tolerated locally than intramuscular route. Therefore, the subcutaneous route is recommended in heavy cattle.
If you notice any serious effects or other effects not mentioned in this package leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Cattle and pig (sow)

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

Cattle:
Respiratory infections:
The recommended dosage is 8 mg marbofloxacin/kg body weight (2 ml product/25 kg BW) in a single injection by intramuscular route. If the volume to be injected is more than 20 ml, it should be divided between two or more injection sites.

In cases of respiratory infections caused by *Mycoplasma bovis*, the recommended dose is 2 mg marbofloxacin/kg body weight (1 ml product/50 kg BW), in a single daily injection for 3 to 5 consecutive days, by intramuscular or subcutaneous route. The first injection may be given by the intravenous route.

Acute mastitis:
The recommended dosage is 2 mg marbofloxacin/kg body weight (1 ml product/50 kg BW) in a single daily injection for 3 consecutive days by intramuscular or subcutaneous route. The first injection may also be given by the intravenous route.

Pig (sow):
The recommended dosage is 2 mg marbofloxacin/kg body weight (1 ml product/50 kg body weight) in a single daily injection for 3 consecutive days by intramuscular route.

Cattle and Pig (sow):
To ensure administration of a correct dose, body weight should be determined as accurately as possible, to avoid underdosing.

In cattle and pig, the preferred injection site is the neck area.
The cap may be safely punctured up to 125 times in case of 100 ml bottle and up to 250 times in case of 250 ml bottle. The user should choose the most appropriate vial size according to the target species to treat.

9. ADVICE ON CORRECT ADMINISTRATION

None

10. WITHDRAWAL PERIOD(S)

Cattle:
2 mg/kg for 3 to 5 days (IV/IM/SC)
Meat and offal: 6 days.
Milk: 36 hours.

8 mg/kg on a single occasion (IM)
Meat and offal: 3 days.
Milk: 72 hours.

Pigs
Meat and offal: 4 days.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Keep the container in the outer carton in order to protect from light.
Do not use this veterinary medicinal product after expiry date which is stated on the label.
Shelf life after first opening the container: 28 days

12. SPECIAL WARNING(S)

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.
Whenever possible, fluoroquinolones should only be used based on susceptibility testing.
Use of the product deviating from the instructions given in the SPC 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.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

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

Pregnancy, lactation:

Laboratory studies in rats and rabbits have not produced any evidence of teratogenic, foetotoxic or maternotoxic effects.

Safety of the product at 2 mg/kg body weight has been established in pregnant cows or in sucking calves and piglets when used in cows and sows. Can be used during pregnancy and lactation.

Safety of the product at 8 mg/kg body weight has not been established in pregnant cows or in sucking calves when used in cows. Therefore, this dose regimen should be used only accordingly to the benefit/risk assessment by the responsible veterinarian.

Interaction with other medicinal products and other forms of interaction:

None known.

Overdose (symptoms, emergency procedures, antidotes):

No sign of overdosage has been observed after administration of 3 times the recommended dose. Overdosage may cause signs such as acute neurological disorders which should be treated symptomatically.

Incompatibilities:
In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

Cardboard box with 1x100 ml vial
Cardboard box with 1x250 ml vial
Not all pack sizes may be marketed.