ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

MARVETIN 100 mg/ml solution for injection for cattle and pigs. (RMS)
Marbofloxacin

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:
Active substance:
Marbofloxacin 100.0 mg

3. PHARMACEUTICAL FORM

Solution for injection.

4. PACKAGE SIZE

100 ml
250 ml

5. TARGET SPECIES

Cattle and pig (sow)

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Cattle: intramuscular, subcutaneous or intravenous use
Pigs (sows): intramuscular use
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal periods:
Cattle:

Indication	**Respiratory**		**Mastitis**
Dosage	2 mg/kg for 3 to 5 days (IV/IM/SC)	8 mg/kg on a single occasion (IM)	2mg/kg for 3 days (IV/IM/SC)
Meat and offal	6 days	3 days	6 days
Milk	36 hours	72 hours	36 hours

Pigs:
Meat and offal: 4 days

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP: {month/year}
Once opened use within 28 days. Once opened use by ...

11. SPECIAL STORAGE CONDITIONS

Keep the container in the outer carton in order to protect from light.

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Dispose of waste material in accordance with local requirements.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only. To be supplied only on veterinary prescription. Administration by a veterinary surgeon (in case of intravenous route) or under their direct responsibility.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Vet-Agro Multi-Trade Company sp. z o.o.
Gliniana 32, 20-616 Lublin, Poland

16. MARKETING AUTHORISATION NUMBER(S)

17. MANUFACTURER'S BATCH NUMBER

Lot:

PARTICULARS TO APPEAR ON THE THE IMMEDIATE PACKAGE

1 vial of 100 ml
1 vial of 250 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

MARVETIN 100 mg/ml solution for injection for cattle and pigs. (RMS)
Marbofloxacin

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:
Active substance:
Marbofloxacin 100.0 mg

3. PHARMACEUTICAL FORM

Solution for injection.

4. PACKAGE SIZE

100 ml
250 ml

5. TARGET SPECIES

Cattle and pig (sow)

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal periods:

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

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP: {month/year}
Once opened use within 28 days.
Once opened use by ...

11. SPECIAL STORAGE CONDITIONS

Keep the container in the outer carton in order to protect from light.

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Dispose of waste material in accordance with local requirements.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only. To be supplied only on veterinary prescription. Administration by a veterinary surgeon (in case of intravenous route) or under their direct responsibility.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Vet-Agro Multi-Trade Company sp. z o.o.
Gliniana 32, 20-616 Lublin, Poland

16. MARKETING AUTHORISATION NUMBER(S)

17. MANUFACTURER'S BATCH NUMBER

Lot:

B. PACKAGE LEAFLET

PACKAGE LEAFLET:

MARVETIN 100 mg/ml solution for injection for cattle and pigs. (RMS)

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 32, 20-616 Lublin, Poland

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

MARVETIN 100 mg/ml solution for injection for cattle and pigs. (RMS)
Marbofloxacin

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

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 cases of hypersensitivity to marbofloxacin, to any other quinolone or to any of the excipients.
Do not use in cases of resistance 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.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

If you notice any side effects, even those not already listed in this package leaflet or you think that the medicine has not worked, please inform your veterinary surgeon.
Alternatively you can report via your national reporting system {national system details}.

7. TARGET SPECIES

Cattle and pig (sow)

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

Cattle: intravenous, intramuscular or subcutaneous use
Pigs (sows): intramuscular use

Cattle:
Respiratory infections:
The recommended dosage is 8 mg marbofloxacin/kg body weight (2 ml veterinary medicinal product/25 kg body weight) in a single injection by the 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 veterinary medicinal product/50 kg body weight), in a single daily injection for 3 to 5 consecutive days, by the 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 veterinary medicinal product/50 kg body weight) in a single daily injection for 3 consecutive days by the 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 veterinary medicinal product/50 kg body weight) in a single daily injection for 3 consecutive days by the 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:

Indication	**Respiratory**		**Mastitis**
Dosage	2 mg/kg for 3 to 5 days (IV/IM/SC)	8 mg/kg on a single occasion (IM)	2mg/kg for 3 days (IV/IM/SC)
Meat and offal	6 days	3 days	6 days
Milk	36 hours	72 hours	36 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 the expiry date which is stated on the label after EXP. The expiry date refers to the last day of that month. Shelf life after first opening the container: 28 days

12. SPECIAL WARNING(S)

Special warnings for each target species:
The efficacy data showed that the product has insufficient efficacy for the treatment of acute forms of mastitis induced by gram-positive bacteria.

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 package 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.

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

Safety of the veterinary medicinal 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 veterinary medicinal 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

Medicines should not be disposed of via wastewater or household waste.
Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

Package sizes:
Cardboard box with 1x100 ml vial
Cardboard box with 1x250 ml vial

Not all pack sizes may be marketed.