ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Box with 1 vial of 50 ml
Box with 1 vial of 100 ml
Box with 1 vial of 250 ml
Box with 6 vials of 100 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

MASTERFLOX 40 mg/ml solution for injection for pigs

Marbofloxacin

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:
Active substance: marbofloxacin 40 mg

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

50 ml
100 ml
250 ml
6 x 100 ml

5. TARGET SPECIES

Pigs (pigs for fattening).

6. INDICATION(S)

---

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Intramuscular use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Withdrawal period:
Pigs
Meat and offal: 6 days.

9. SPECIAL WARNINGS, IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month /year}

Once broached, use by _____
Shelf-life after first broaching the container: 28 days.

11. SPECIAL STORAGE CONDITIONS

Store in the original package. Protect from light.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS ORWASTE MATERIALS, IF ANY

Disposal: read the package leaflet.

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.

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

FATRO S.p.A. - Via Emilia, 285 - Ozzano dell'Emilia (Bologna), Italy.

16. MARKETING AUTHORISATION NUMBERS

Vm 11557/4001

17. MANUFACTURER'S BATCH NUMBER

Batch {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

50 ml label

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

MASTERFLOX 40 mg/ml solution for injection for pigs

Marbofloxacin.

2. QUANTITY OF THE ACTIVE SUBSTANCE

Each ml contains: marbofloxacin 40 mg.

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

50 ml vial

4. ROUTE(S) OF ADMINISTRATION

Intramuscular use.

5. WITHDRAWAL PERIOD

Withdrawal period:
Pigs
Meat and offal: 6 days.

6. BATCH NUMBER

Batch {number}

7. EXPIRY DATE

EXP{month /year}

Once broached, use by _____

Shelf-life after first broaching the container: 28 days.

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

100 ml, 250 ml label

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

MASTERFLOX 40 mg/ml solution for injection for pigs

Marbofloxacin.

2. STATEMENT OF THE ACTIVE SUBSTANCES

Each ml contains:
Active substance: marbofloxacin 40 mg

3. PHARMACEUTICAL FORM

Solution for injection.

4. PACKAGE SIZE

100 ml
250 ml

5. TARGET SPECIES

Pigs (pigs for fattening).

6. INDICATION(S)

---

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Intramuscular use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Withdrawal period:
Pigs
Meat and offal: 6 days.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}

Once broached, use by _____.

Shelf-life after first broaching the container: 28 days.

11. SPECIAL STORAGE CONDITIONS

Store in the original package. Protect from light.

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

Disposal: read package leaflet.

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.

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

FATRO S.p.A. - Via Emilia, 285 - Ozzano dell'Emilia (Bologna), Italy.

16. MARKETING AUTHORISATION NUMBERS

Vm 11557/4001

17. MANUFACTURER'S BATCH NUMBER

Batch {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

MASTERFLOX 40 mg/ml solution for injection for 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:
FATRO S.p.A.
Via Emilia, 285
Ozzano dell'Emilia (Bologna), Italy.

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

MASTERFLOX 40 mg/ml solution for injection for pigs.

Marbofloxacin.

3. STATEMENT OF THE ACTIVE SUBSTANCE AND OTHER INGREDIENTS

Each ml contains:

Active substance:
Marbofloxacin 40 mg

Excipients:
Disodium edetate 0.1 mg

Clear yellow solution for injection.

4. INDICATIONS

Treatment of respiratory infections caused by strains of *Actinobacillus pleuropneumoniae, Pasteurella multocida, Mycoplasma hyopneumoniae* susceptible to marbofloxacin.

5. CONTRAINDICATIONS

Do not use in cases where the pathogen involved is resistant to marbofloxacin and other (fluoro)quinolones (cross-resistance).

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

6. ADVERSE REACTIONS

Transient local reactions such as oedema, pain and swelling at the injection site and inflammatory lesions, which may persist for 6 days, may be uncommonly caused by intramuscular administration.
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.

7. TARGET SPECIES

Pigs (pigs for fattening).

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

For intramuscular use.

The recommended dosage is 2 mg marbofloxacin/kg body weight (equivalent to 0.5 ml of veterinary medicinal product/ 10 kg body weight) in a single daily intramuscular injection, for 3-5 consecutive days.

9. ADVICE ON CORRECT ADMINISTRATION

To ensure administration of a correct dose, body weight should be determined as accurately as possible, to avoid underdosing.

The preferred injection site is the neck area.

The vial may be broached up to 20 times.
The user should choose the most appropriate vial size according to the bodyweight and number of animals to be treated**.**

10. WITHDRAWAL PERIOD

Pigs
Meat and offal: 6 days.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Store in the original package. Protect from light.
Do not use this veterinary medicinal product after the expiry date which is stated on the carton and vial label after “EXP”. The expiry date refers to the last day of that month.
Shelf-life after first broaching the container: 28 days
When the vial is broached for the first time, the date on which any product remaining in the vial is to be discarded should be filled out in the space provided on the label.

12. SPECIAL WARNINGS

Special precautions for use

This product does not contain any antimicrobial preservative.

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.

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

(Fluoro)quinolones may cause hypersensitivity (allergy) in sensitised people. People with known hypersensitivity to (fluoro)quinolones or any of the excipients should avoid any contact with the veterinary medicinal product.
Avoid contact of the skin and eyes with the product. In case of accidental spillage onto skin or eyes, rinse the affected area with large amounts of water.
Avoid accidental self-injection, since this can cause local irritation.
In case of self-injection or ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.
Wash hands after use.

Pregnancy and lactation

Laboratory studies in rats and rabbits have not produced any evidence of teratogenic, foetotoxic or maternotoxic effects.
Use only according to the benefit-risk assessment by the responsible veterinarian.
The product is intended only for pigs for fattening.

Interaction with other medicinal products and other forms of interaction

None known.

Overdose (symptoms, emergency procedures, antidotes)

No signs of overdosage have been observed administering marbofloxacin up to 3 times the recommended dose.
Overdose may cause acute signs in the form of neurological disorders which should be treated symptomatically. Do not exceed the recommended dose.

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 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

To be completed nationally.

15. OTHER INFORMATION

Pack sizes:
Box with 1 vial of 50 ml
Box with 1vial of 100 ml
Box with 1 vial of 250 ml
Box with 6 vials of 100 ml

Not all pack sizes may be marketed.

Veterinary use. To be supplied only on veterinary prescription.

Administration by a veterinary surgeon or under their direct responsibility.

Approved: 29 March 2019