B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Masterflox 40 mg/ml solution for injection for pigs.

2. Composition

Each ml contains:

Active substances:
Marbofloxacin 40 mg

Excipients:
Disodium edetate 0.1 mg

Clear yellow solution, with no visible particles.

3. Target species

Pigs (for fattening).

4. Indications for use

Treatment of respiratory infections caused by sensitive 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. Special warnings

Special warnings:
This veterinary medicinal product does not contain any antimicrobial preservative.

Special precautions for safe use in the target species:

Official and local antimicrobial policies should be taken into account when the veterinary medicinal 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 veterinary medicinal 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 should avoid contact with the veterinary medicinal product.
Avoid contact of the skin and eyes with the veterinary medicinal 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 accidental 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 veterinary medicinal product is intended only for pigs for fattening.

Interaction with other medicinal products and other forms of interaction:
None known.

Overdose:

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.

Special restrictions for use and special conditions for use:

Major incompatibilities:

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

7. Adverse events

Pigs (for fattening)

Uncommon (1 to 10 animals / 1 000 animals treated)	Injection site reaction (e.g. injection site oedema[1]; injection site pain[1]; injection site swelling[1]; injection site inflammation[2])

[1] Transient.
[2] Can last up to 6 days.

Reporting adverse events is important. It allows continuous safety monitoring of a product. 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 contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder <or its local representative> using the contact details at the end of this leaflet, or via your national reporting system:

8. Dosage for each species, routes 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 a correct dosage, body weight should be determined as accurately as possible.

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 periods

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 after Exp.
The expiry date refers to the last day of that month.
Shelf life after first opening the immediate packaging: 28 days.

12. Special precautions for disposal

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

Package sizes:
Cardboard box with 1 vial of 50 ml
Cardboard box with 1vial of 100 ml
Cardboard box with 1 vial of 250 ml
Cardboard box with 6 vials of 100 ml

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

{MM/YYYY}

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

16. Contact details

Marketing authorisation holder and manufacturer responsible for batch release <and contact details to report suspected adverse events>:

FATRO S.p.A.
Via Emilia, 285
40064 Ozzano dell'Emilia (Bologna), Italy.
Tel: +39 051 6512711

<Local representatives and contact details to report suspected adverse events:>

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

17. Other information