

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Masterflox 40 mg/ml solution for injection for pigs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substances:

Marbofloxacin 40 mg

Excipients:

Qualitative composition of excipients and other constituents	Quantitative composition if that information is essential for proper administration of the veterinary medicinal product
Disodium edetate	0.1 mg
Gluconolactone	
Mannitol	
Water for injections	

Clear yellow solution, with no visible particles.

3. CLINICAL INFORMATION

3.1 Target species

Pigs (for fattening).

3.2 Indications for use for each target species

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

3.3 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.

3.4 Special warnings

None.

3.5 Special precautions for use

This veterinary medicinal product does not contain an 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.

Special precautions for the protection of the environment:

Not applicable.

3.6 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)
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¹ Transient.

² Can last up to 6 days.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

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.

3.8 Interaction with other medicinal products and other forms of interaction

None known.

3.9 Administration routes and dosage

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.

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.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

No signs of overdosage have been observed administering marbofloxacin at 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.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Pigs

Meat and offal: 6 days.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code : QJ01MA93

4.2 Pharmacodynamics

Marbofloxacin is a synthetic bactericidal antimicrobial belonging to the fluoroquinolone group, which acts by inhibition of DNA gyrase and topoisomerase IV. It has a broad-spectrum activity *in vitro* against Gram-positive bacteria, Gram-negative bacteria (*Pasteurella multocida* and *Actinobacillus pleuropneumoniae*) and against genus *Mycoplasma* (*Mycoplasma hyopneumoniae*).

It should be noted that some strains of Streptococci, Pseudomonas and Mycoplasma may not be sensitive to marbofloxacin. Marbofloxacin is not active against anaerobes, yeast or fungi.

Between 2015 and 2016, MICs of marbofloxacin were determined against 171 strains of *Pasteurella multocida* and 164 strains of *Actinobacillus pleuropneumoniae* isolated from pig respiratory diseases (Morrissey, 2019) while during the years 2010-2012 *in vitro* activity of marbofloxacin was assessed on 50 strains of *Mycoplasma hyopneumoniae* isolated from pig respiratory diseases (Klein *et al.*, 2017). The results of MIC₅₀, MIC₉₀ and MIC range are reported in the table below:

Target respiratory bacteria	Number of EU strains tested	MIC ₅₀ (µg/ml)	MIC ₉₀ (µg/ml)	MIC range (µg/ml)
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<i>Pasteurella multocida</i>	171	0.015	0.03	0.004-1
<i>Actinobacillus pleuropneumoniae</i>	164	0.03	0.12	0.008-2
<i>Mycoplasma hyopneumoniae</i>	50	0.03	0.5	0.002-1

Strains with MIC \leq 1 μ g/ml are susceptible to marbofloxacin whereas strains with MIC \geq 4 μ g/ml are resistant to marbofloxacin according to the clinical breakpoints for Pasteurellaceae defined by the “Comité de l’Antibiogramme de la Société Française de Microbiologie” (= French Society of Microbiology”) (CA-SFM, 2018).

Resistance to fluoroquinolones occurs by chromosomal mutations with following mechanisms: decrease of the bacterial cell wall permeability, expression change of genes coding for efflux pumps or mutations in genes encoding enzymes responsible for molecule binding. Plasmid-mediated resistance to fluoroquinolones confer only decreased susceptibility of bacteria, however, it can facilitate development of mutations in genes of target enzymes and can be transferred horizontally. Depending on the underlying resistance mechanism cross-resistance to other (fluoro)quinolones and co-resistance to other antimicrobial classes can occur.

4.3 Pharmacokinetics

After intramuscular administration in swine at the recommended dose of 2 mg/kg body weight, marbofloxacin is rapidly absorbed and reaches its maximum plasma concentration of 1.5 μ g/ml in less than one hour.

Marbofloxacin is readily absorbed and its bioavailability is close to 100%. It is weakly bound to plasma proteins (less than 10%), extensively distributed and in most tissues (liver, kidney, lungs, bladder, uterus, digestive tract) it achieves higher concentrations than in plasma.

Marbofloxacin is eliminated slowly ($t_{1/2}$ = 8-10 hours) predominantly in the active form in urine (2/3) and faeces (1/3).

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

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

5.2 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf-life after first opening the immediate packaging: 28 days.

5.3 Special precautions for storage

Store in the original package.
Protect from light.

5.4 Nature and composition of immediate packaging

Amber type II glass vials, closed with chlorobutyl rubber stopper type I and aluminium collar, in a cardboard box.

Package sizes:

Cardboard box with 1 vial of 50 ml
Cardboard box with 1 vial 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.

5.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

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 national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

FATRO S.p.A.

7. MARKETING AUTHORISATION NUMBER(S)

VPA10836/003/001

8. DATE OF FIRST AUTHORISATION

24/07/2015

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

19/03/2026

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

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