[Version 9.1, 11/2024]

ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

FORCYL swine 160 mg/ml solution for injection for pigs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:
Marbofloxacin ..... 160 mg

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Benzyl alcohol (E1519)	15 mg
Glucono-delta-lactone	
Water for injections	

Clear yellow greenish to yellow brownish solution.

3. CLINICAL INFORMATION

3.1 Target species

Pigs (for fattening, weaned piglets, sows).

3.2 Indications for use for each target species

In fattening pigs:
- Treatment of respiratory tract infections caused by susceptible strains of *Actinobacillus pleuropneumoniae* and *Pasteurella multocida.*

In weaned piglets:
- Treatment of intestinal infections caused by susceptible strains of *E. coli.*

In post-partum sows:
- Treatment of metritis mastitis agalactia syndrome (form of postpartum dysgalactiae syndrome, PPDS) caused by susceptible strains of *E. coli*.

3.3 Contraindications

Do not use in cases of hypersensitivity to the active substance, other fluoroquinolones or to any of the excipients.
Do not use fluoroquinolones as prophylaxis or metaphylaxis to prevent diarrhoea at weaning, to limit development of resistance.

3.4 Special warnings

Do not use in cases where the pathogen involved is resistant to other fluoroquinolones (cross resistance).

3.5 Special precautions for use

Special precautions for safe use in the target species:

Official and local antimicrobial policies should be taken into account when this 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. Wherever possible, use of the veterinary medicinal product should only be based on susceptibility testing.
Use of the veterinary medicinal product deviating from the instructions given in this 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:

People with known hypersensitivity to (fluoro)quinolones and benzyl alcohol should avoid contact with the veterinary medicinal product.
Wash hands after use. Avoid contact of the skin and eyes with the product. If the product comes into contact with the skin or eyes, rinse with copious amounts of water.
Care should be taken to avoid accidental self-injection. In case of accidental self-administration, the user should seek medical advice immediately and show the package leaflet or the label to the physician.
Accidental self-injection can induce a slight irritation.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Swine:

Common (more than 1 but less than 10 animals in 100 animals)	Injection site pain
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Injection site reaction[1]

[1] Disappear within 36 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

The safety of the veterinary medicinal product has not been established at 8 mg/kg in pregnant sows or in suckling piglets when used in sows.

Pregnancy and lactation:

Laboratory studies in rats and rabbits have not produced any evidence of teratogenic, embryotoxic or maternotoxic effect.
Use only according to the benefit-risk assessment by the responsible veterinarian.

3.8 Interaction with other medicinal products and other forms of interaction

None known.

3.9 Administration routes and dosage

Intramuscular use.

The recommended dosage is 8 mg of marbofloxacin /kg body weight i.e. 1 ml of veterinary medicinal product/20 kg body weight in a single intramuscular injection in the side of the pig neck.
To ensure a correct dosage, body weight should be determined as accurately as possible.

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

Lesions of the joint cartilage, potentially leading to difficulties in movement, were observed in some animals treated at three times the recommended dose and treatment duration.

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

Meat and offal: 9 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. It has a broad-spectrum activity in vitro against Gram-positive bacteria and, Gram-negative bacteria.

Between 2009 and 2013, the activity of marbofloxacin against *Pasteurella multocida* (n=444) and Escherichia coli (n=1226) isolated from swine diseases in Europe was for P. multocida: MIC range: 0,004-1 microgram/ml, MIC50: 0.013microgram/mlMIC90: 0,028 microgram/ml and for E. coli (digestive infections): MIC range 0,008-64microgram/ml; MIC50: 0,026microgram/ml; MIC90: 0,681microgram/ml, for E. coli (MMA syndrome): MIC range 0,015-16microgram/ml; MIC50: 0,024µg/ml; MIC90: 0,475microgram/ml. Marbofloxacin MIC distribution among E. coli strains isolated from digestive or MMA syndrome are similar with a trimodal distribution.

The clinical breakpoints defined for marbofloxacin are S = 1 microgram/mL, I = 2 microgram/mL and R = 4 microgram/mL for Pasteurellaceae according to the “Comité de l’Antibiogramme de la Société Française de Microbiologie” (=French Society of Microbiology) (CA-SFM 2013).

Between 2009 and 2012, the activity of marbofloxacin against *Actinobacillus pleuropneumoniae* (n=157) isolated from swine diseases in Europe was: MIC range: 0.015-2microgram/mL, MIC50: 0.03microgram/mL, MIC90: 0.06microgram/mL
The activity of marbofloxacin against the target bacterial species is bactericidal concentration dependent.

A decrease of susceptibility of *Campylobacter spp.* against fluoroquinolones was observed since 1999.

Resistance to fluoroquinolones occurs by chromosomal mutation with three mechanisms: decrease of the bacterial wall permeability, expression of efflux pump or mutation of enzymes responsible for molecule binding. To date, only sporadic cases have been reported for plasmid mediated fluoroquinolone resistance in animals. 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 administration of an intramuscular dose of 8 mg/kg, the following mean plasmatic pharmacokinetic parameters were observed:

Parameter	Fattening pigs	Weaned pigs	Sows
T_{max}	0.95 h	0.93 h	1 h
C_{max}	6.295 µg/mL	5.550 µg/mL	5.809 µg/mL
AUC_{INF}	114.7 µg.h/mL	79.89 µg.h/mL	112.0 µg.h/mL
T½lz	15.14 h	13.23 h	11.92 h
F	91.53 %	89.57 %	nc

C_{max} = maximal plasmatic concentration;T_{max} = mean observed occurrence time of the Cmax; AUC_{INF} = area under the concentration-time curve extrapolated to infinity; T½lz = mean elimination half-life; F mean absolute bioavailability; nc: not calculated

Marbofloxacin is extensively distributed. Uterus tissue concentrations in sows reach Cmax of 9.346 microgram/g in the uterine body observed at Tmax of 1.00 hour after administration and the AUClast was 105.4 microgram.h/g.
Binding to plasma proteins is weak, about 4%. In pigs, the elimination is predominantly as the active form in urine and faeces.
Marbofloxacin is eliminated slightly faster in post-weaning piglets than in heavier animals.

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: 3 years.
Shelf life after first opening the immediate packaging: 28 days.

5.3 Special precautions for storage

This veterinary medicinal product does not require any special storage conditions.

5.4 Nature and composition of immediate packaging

Amber type II glass vials
Chlorobutyl rubber stopper
Aluminium cap or flip cap

Pack sizes:
Cardboard box containing one 50 ml vial
Cardboard box containing one 100 ml vial
Cardboard box containing one 250 ml vial

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

7. MARKETING AUTHORISATION NUMBER(S)

8. DATE OF FIRST AUTHORISATION

DD/MM/YYYY

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

MM/YYYY

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).

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box of 50 ml / 100 ml / 250 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Forcyl swine 160 mg/ml solution for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Marbofloxacin ……160 mg/ml

3. PACKAGE SIZE

Vial of 50 ml
Vial of 100 ml
Vial of 250 ml

4. TARGET SPECIES

Pigs (for fattening, weaned piglets, sows).

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Intramuscular use.

7. WITHDRAWAL PERIODS

Withdrawal periods: Meat and offal: 9 days.

8. EXPIRY DATE

Exp. {mm/yyyy}
Once broached use by 28 days.

9. SPECIAL STORAGE PRECAUTIONS

10. THE WORDS "READ THE PACKAGE LEAFLET BEFORE USE"

Read the package leaflet before use.

11. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

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

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

14. MARKETING AUTHORISATION NUMBERS

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Label of 100 and 250 ml vials

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Forcyl swine 160 mg/ml solution for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Marbofloxacin ……..…160 mg/ml

3. TARGET SPECIES

Pigs (for fattening, weaned piglets, sows).

4. ROUTES OF ADMINISTRATION

Intramuscular use.
Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Withdrawal periods: Meat and offal: 9 days.

6. EXPIRY DATE

Exp. {mm/yyyy}
Once broached use by 28 days.
Once broached, use by:

7. SPECIAL STORAGE PRECAUTIONS

8. NAME OF THE MARKETING AUTHORISATION HOLDER

9. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Label of 50 ml vials

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Forcyl swine 160 mg/ml solution for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Marbofloxacin ……..…160 mg/ml

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}
Once broached use by 28 days.
Once broached, use by:

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Forcyl Swine 160 mg/ml solution for injection for pigs

2. Composition

One ml contains:

Active substance:
Marbofloxacin ..... 160 mg

Excipients:
Benzyl alcohol (E1519).....15 mg

Clear yellow greenish to yellow brownish solution.

3. Target species

Pigs (for fattening, weaned piglets, sows).

4. Indications for use

In fattening pigs:
- Treatment of respiratory tract infections caused by susceptible strains of *Actinobacillus pleuropneumoniae* and *Pasteurella multocida*

In weaned piglets:
- Treatment of intestinal infections caused by susceptible strains of *E. coli*

In post-partum sows:
- Treatment of metritis mastitis agalactia syndrome (form of postpartum dysgalactiae syndrome, PPDS) caused by susceptible strains of *E. coli*.

5. Contraindications

Do not use in cases of hypersensitivity to the active substance, other fluoroquinolones or to any of the excipients.
Do not use fluoroquinolones as prophylaxis or metaphylaxis to prevent diarrhoea at weaning, to limit development of resistance.

6. Special warnings

Special warnings:

Do not use in cases where the pathogen involved is resistant to other fluoroquinolones (cross resistance).

Special precautions for safe use in the target species:

Official and local antimicrobial policies should be taken into account when this veterinary medicinal 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. Wherever possible, use of the veterinary medicinal product should only be based on susceptibility testing.
Use of the veterinary medicinal product deviating from the instructions given in this 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:

People with known hypersensitivity to (fluoro)quinolones and benzyl alcohol should avoid contact with the veterinary medicinal product.
Wash hand after use. Avoid contact of the skin and eyes with the product. If the product comes into contact with the skin or eyes, rinse with copious amounts of water.
Care should be taken to avoid accidental self-injection. In case of accidental self-administration the user should seek medical advice immediately and show the package leaflet or the label to the physician.
Accidental self-injection can induce a slight irritation.

Special precautions for the protection of the environment:
Not applicable.

Pregnancy and lactation:
The safety of the veterinary medicinal product at 8 mg/kg has not been established at 8 mg/kg in pregnant sows or in suckling piglets when used in sows.
Laboratory studies in rats and rabbits have not produced any evidence of a teratogenic, embryotoxic or maternotoxic effect
Use only according to the benefit/risk assessment carried out by the responsible veterinarian.

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

Overdose:
Lesions of the joint cartilage, potentially leading to difficulties in movement, were observed in some animals treated at 24 mg/kg for three times the recommended dose and treatment duration.

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

7. Adverse events

Swine:

Common (more than 1 but less than 10 animals in 100 animals):
Injection site pain
Very rare (<1 animal / 10,000 animals treated, including isolated reports):
Injection site reaction[1]

[1] Disappear within 36 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 the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system: {national system details}.

8. Dosage for each species, routes and method of administration

Intramuscular use.

The recommended dosage is 8 mg of marbofloxacin /kg body weight i.e. 1 ml of veterinary medicinal product/20 kg body weight in a single intramuscular injection in the side of the pig neck.
To ensure a correct dosage, body weight should be determined as accurately as possible.

9. Advice on correct administration

None.

10. Withdrawal periods

Meat and offal: 9 days.

11. Special storage precautions

Keep out of the sight and reach of children.
This veterinary medicinal product does not require any special storage conditions.
Shelf life after first opening the immediate packaging: 28 days.
Do not use this veterinary medicinal product after the expiry date stated on the carton and label after Exp. The expiry date refers to the last day of that month.

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.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack 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

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:

Manufacturer responsible for batch release:

Vetoquinol S.A.
Magny vernois
70200 Lure
France

or

Vetoquinol Biowet Sp. z o.o.
ul. Kosynierów Gdyńskich 13-14
66-400 Gorzów Wielkopolski
Poland

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.