[Version 9,03/2022] corr. 11/2022

ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

MARBOCYL 20 mg/ml solution for injection for cattle and pigs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance :
Marbofloxacin ..... 20.0 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
Thioglycerol	0.5 mg
m-crésol	2.0 mg
Gluconolactone	
Mannitol	
Water for injection	

Solution for injection.
Yellow-greenish to yellow-brownish aqueous solution.

3. CLINICAL INFORMATION

3.1 Target species

Cattle and Pigs (for fattening).

3.2 Indications for use for each the target species

In preruminating and ruminating calves

Treatment of respiratory infections caused by sensitive strains of *Pasteurella multocida, Mannheimia (Pasteurella) haemolytica* and *Mycoplasma bovis.*

In pigs

Treatment of respiratory infections caused by sensitive strains of *Actinobacillus pleuropneumoniae, Mycoplasma hyopneumoniae, Pasteurella multocida.*
The veterinary medicinal product should only be used based on susceptibility testing.

3.3 Contraindications

Bacterial infections with resistance to other fluoroquinolones (cross resistance).
Do not use in cases of hypersensitivity to the active substances, other quinolone, or to any of the excipients.

3.4 Special warnings for each target species

None.

3.5 Special precautions for use

Special precautions for use in animals

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 official and local antimicrobial policies should be taken into account when the veterinary medicinal product is used.
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

None

Other precautions

None

3.6 Adverse events

Calves and pigs:

Undetermined frequency (cannot be estimated from the available data):	Injection site œdema[1] ; injection site pain[2]; injection site lesion[2,3]

[1] Transient reaction, in case of subcutaneous or intramuscular administration.
[2] In case of intramuscular administration
[3] Inflammatory lesions can last up to 6 days in pigs and 12 days in calves.

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, embryotoxic, maternotoxic effects.
Use only according to the benefit-risk assessment by the responsible veterinarian.
See also paragraph 3.12.

3.8 Interaction with other medicinal products and other forms of interaction

Unknown.

3.9 Administration routes and dosage

For s.c., i.m., and i.v. route

In preruminating and ruminating calves

The recommended dosage is 2 mg/kg/day (1 ml/10 kg) in a single daily injection by subcutaneous or intramuscular route, for 3 to 5 days. The first injection may also be given by the intravenous route.

In pigs
Treatment of respiratory diseases: the recommended dosage is 2 mg/kg (1 ml/10 kg bw) in a single daily injection by the intramuscular route, for 3 to 5 days.

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

No sign of overdosage has been observed with the marbofloxacin after administration of 3 times the recommended dose.
Overdosage may cause signs in the form of acute neurological disorders which would have to be treated symptomatically.

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

For administration only by a veterinarian.

3.12 Withdrawal periods

	preruminating and ruminating calves	**Pigs**
Meat and offals	6 days	4 days

The veterinary medicinal product is not authorised for use in lactating animals producing milk for human consumption.

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 is effective against a wide range of Gram positive bacteria (in particular *Staphylococci*) and Gram negative bacteria (*Escherichia coli, Pasteurella multocida, Pasteurella haemolytica* and *Actinobacillus pleuropneumoniae)* as well as *Mycoplasma (Mycoplasma bovis, Mycoplasma hyopneumoniae).*
Resistance to *Streptococcus* may occur.

4.3 Pharmacokinetics

After subcutaneous or intramuscular administration in cattle and pigs at the recommended dose of 2

mg/kg, marbofloxacin is readily absorbed and reaches maximal plasma concentrations of 1,5 µg/ml within less than 1 hour.
Its bioavailability is close to 100%.
Marbofloxacin is weakly bound to plasma proteins (less than 10 % in pigs and 30 % in cattle), extensively distributed and in most tissues (liver, kidney, skin, lung, uterus) it achieves higher concentrations than in plasma.
Marbofloxacin is eliminated slowly in pre-ruminating calves ($t_{1/2}$ = 5-9 hours) and pigs ($t_{1/2}$ = 8-10 hours), faster in ruminant cattle ($t_{1/2}$ = 4-7 hours) predominantly in the active form in urine and faeces.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Do not mix with any other veterinary medicinal product for use with the veterinary medicinal product.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 24 months.
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 Special precautions for storage

Primary packaging
Amber type II glass vials chlorobutyl rubber stoppers Aluminium oversealed caps.

Presentation
Box of one vial of 10 ml
Box of one vial of 20 ml
Box of one vial of 50 ml
Box of one vial of 100 ml
Box of one vial of 250 ml

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

To be completed nationally.

7. MARKETING AUTHORISATION NUMBER(S)

To be completed nationally.

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: DD/MM/YYYY

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

MM/YYYY

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

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

CARTON BOX
10/20/50/100/250 ml glass vial

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

MARBOCYL 20 mg/ml solution for injection for cattle and pigs

2. STATEMENT OF ACTIVE SUBSTANCES

Marbofloxacin ..... 20.0 mg

3. PACKAGE SIZE

10 ml
20 ml
50 ml
100 ml
250 ml

4. TARGET SPECIES

Cattle and Pigs (for fattening).

5. INDICATIONS

Read the package leaflet before use.

6. ROUTES OF ADMINISTRATION

For s.c., i.m., and i.v. route

In preruminating and ruminating calves:
The recommended dosage is 2 mg/kg/day (1 ml/10 kg) in a single daily injection by subcutaneous or intramuscular route, for 3 to 5 days. The first injection may also be given by the intravenous route.

In pigs:
Treatment of respiratory diseases: the recommended dosage is 2 mg/kg (1 ml/10 kg bw) in a single daily injection by the intramuscular route, for 3 to 5 days.

7. WITHDRAWAL PERIODS

	preruminating and ruminating calves	**Pigs**

Meat and offals	6 days	4 days

Not authorised for use in animals producing milk for human consumption.

8. EXPIRY DATE

Exp. {mm/yyyy}

Once broached, use within 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

To be completed nationally.

14. MARKETING AUTHORISATION NUMBERS

To be completed nationally.
EU/0/00/000/000

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Label of 50, 100, 250 ml vials

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

MARBOCYL 20 mg/ml solution for injection for cattle and pigs

2. STATEMENT OF ACTIVE SUBSTANCES

Marbofloxacin ..... 20.0 mg

3. TARGET SPECIES

Cattle and Pigs (for fattening).

4. ROUTES OF ADMINISTRATION

Read the package leaflet before use.

5. WITHDRAWAL PERIODS

	preruminating and ruminating calves	**Pigs**
Meat and offals	6 days	4 days

Not authorised for use in animals producing milk for human consumption.

6. EXPIRY DATE

Exp. {mm/yyyy}

Once broached, use within 28 days.

7. SPECIAL STORAGE PRECAUTIONS

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

8. NAME OF THE MARKETING AUTHORISATION HOLDER

To be completed nationally.

9. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Label of 10 and 20 ml vials

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

MARBOCYL 20 mg/ml solution for injection for cattle and pigs

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Marbofloxacin ..... 20.0 mg

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

Once broached, use within 28 days.

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

MARBOCYL 20 mg/ml solution for injection for cattle and pigs

2. Composition

Each ml contains:

Active substance :
Marbofloxacin ..... 20.0 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
Thioglycerol	0.5 mg
m-crésol	2.0 mg

3. Target species

Cattle and Pigs (for fattening).

4. Indications for use

In preruminating and ruminating calves
Treatment of respiratory infections caused by sensitive strains of *Pasteurella multocida*, *Mannheimia (Pasteurella) haemolytica* and *Mycoplasma bovis*.

In pigs
Treatment of respiratory infections caused by sensitive strains of *Actinobacillus pleuropneumoniae, Mycoplasma hyopneumoniae, Pasteurella multocida*.
The veterinary medicinal product should only be used based on susceptibility testing.

5. Contraindications

Bacterial infections with resistance to other fluoroquinolones (cross resistance).
Do not use in cases of hypersensitivity to the active substances, other quinolone, or to any of the excipients.

6. Special warnings

Special warnings:
None.

Special precautions for safe use in the target species:
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 official and local antimicrobial policies should be taken into account when the veterinary medicinal product is used.
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:
None

Pregnancy and lactation:
Studies in laboratory animals (rats, rabbits) did not show any teratogenic, embryotoxic effects or any maternal toxicity of marbofloxacin.
To be used only according to the risk/benefit assessment by the veterinarian.
In the case of use in the cow during lactation, see paragraph «Withdrawal Period».

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

Overdose:
No sign of overdosage has been observed after administration of 3 times the recommended dose.
Overdosage may cause signs in the form of acute neurological disorders which would have to be treated symptomatically.

Major incompatibilities:
Do not mix with other medicinal products.

7. Adverse events

Calves and pigs:

Undetermined frequency (cannot be estimated from the available data):	Injection site œdema[1] ; injection site pain[2]; injection site lesion[2,3]

[1] Transient reaction, in case of subcutaneous or intramuscular administration.
[2] In case of intramuscular administration
[3] Inflammatory lesions can last up to 6 days in pigs and 12 days in calves.

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:
France
Agence Nationale du Médicament Vétérinaire (ANMV)
Site internet : https://pharmacovigilance-anmv.anses.fr/

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

For s.c., i.m., and i.v. route

In preruminating and ruminating calves

The recommended dosage is 2 mg/kg/day (1 ml/10 kg) in a single daily injection by subcutaneous or intramuscular route, for 3 to 5 days. The first injection may also be given by the intravenous route.

In pigs
Treatment of respiratory diseases: the recommended dosage is 2 mg/kg (1 ml/10 kg bw) in a single daily injection by the intramuscular route, for 3 to 5 days.

9. Advice on correct administration

10. Withdrawal periods

	preruminating and ruminating calves	Pigs
Meat and offals	6 days	4 days

Not authorised for use in animals producing milk for human consumption.

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.

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

To be completed nationally.

Box of one vial of 10 ml
Box of one vial of 20 ml

Box of one vial of 50 ml
Box of one vial of 100 ml
Box of one vial of 250 ml

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: To be completed nationally.

Manufacturer responsible for batch release and contact details to report suspected adverse reactions:
Vetoquinol S.A.
MAGNY-VERNOIS
F-70200 LURE
FRANCE

Or

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

Contact details to report suspected adverse reactions:
To be completed nationally.