ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Marbofloxacin Support Pharma 40 mg/ml solution for injection for pigs (AT, CY, CZ, DE, EE, EL, ES, IE, IT, LT, LV, PL, PT, SK)
Marbofloxacin 40 mg/ml solution for injection for pigs (UK)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1 ml contains:

Active substance:
Marbofloxacin 40 mg.

Excipients:
disodium edetate 0.1 mg

For a full list of the excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Solution for injection.
Clear yellow solution, with no visible particles.

4. CLINICAL PARTICULARS

4.1. Target species

Pig (pig for fattening).

4.2. Indications for use, specifying the target species

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

4.3. Contraindications

Do not use in cases where the pathogen involved is resistant to marbofloxacin and other (fluoro)quinolones (cross-resistance).
Do not administer to animals known to be hypersensitive to marbofloxacin, other quinolones, or to any of the excipients.

4.4. Special warnings for each target species

None.

4.5. Special precautions for use

This product does not contain an 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

People with known hypersensitivity to (fluoro)quinolones or any of the excipients should avoid 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.

4.6. Adverse reactions (frequency and seriousness)

Intramuscular administration may cause transient local reactions such as oedema, pain and swelling at the injection site and inflammatory lesions which may persist for 6 days.

4.7. Use during pregnancy, lactation or lay

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.

4.8. Interaction with other medicinal products and other forms of interaction

None known.

4.9. Amounts to be administered and administration route

For intramuscular use.

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

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**.**

4.10. Overdose (symptoms, emergency procedures, antidotes), if necessary

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.

4.11. Withdrawal period(s)

Pigs
Meat and offal: 6 days.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antibacterials for systemic use, Fluoroquinolones.

ATC Vet code: QJ01MA93.

5.1. Pharmacodynamic properties

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, Gram-negative bacteria (*Pasteurella multocida* and *Actinobacillus pleuropneumoniae*) and against Mycoplasmas *(Mycoplasma hyopneumoniae).*
Resistance to *Streptococcus* spp may occur.
Strains with MIC $\leq$ 1 µg/ml are susceptible to marbofloxacin whereas strains with MIC $\geq$ 4 µg/ml are resistant to Marbofloxacin.
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.

5.2. Pharmacokinetic particulars

After intramuscular administration in swine at the recommended dose of 2 mg/kg b.w., marbofloxacin is rapidly absorbed and reaches its maximum plasma concentration of 1.5 µg/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).

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Disodium edetate
Gluconolactone
Mannitol
Water for injections

6.2. Incompatibilities

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

6.3. 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.

6.4. Special precautions for storage

Store in the original package. Protect from light.
This veterinary medicinal product does not require any special temperature storage conditions.

6.5. Nature and composition of immediate packaging

50 ml, 100 ml, 250 ml amber type II glass vials, closed with chlorobutyl rubber stopper type I and aluminium collar.
Cardboard box containing 1 x 50 ml, 1 x 100 ml, 1 x 250 ml and 6 x 100 ml. Not all packs may be marketed.

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

Any unused veterinary medicinal products or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Laboratorios Support Pharma, S.L.
General Alvarez de Castro, 39
28010 Madrid, Spain

8. MARKETING AUTHORISATION NUMBER(S)

9. DATE OF FIRST AUTHORISATION

Date of first authorisation:

10. DATE OF REVISION OF THE TEXT

{MM/YYYY} or <month YYYY>

PROHIBITION OF SALE, SUPPLY AND/OR USE

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Marbofloxacin Support Pharma 40 mg/ml solution for injection for pigs (AT, CY, CZ, DE, EE, EL, ES, IE, IT, LT, LV, PL, PT, SK)
Marbofloxacin 40 mg/ml solution for injection for pigs (UK)

Marbofloxacin

2. STATEMENT OF THE ACTIVE AND OTHER SUBSTANCES

1 ml contains:
Active substance: marbofloxacin 40 mg - **Excipients:** disodium edetate 0.1 mg

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

50 ml
100 ml
250 ml
6 x 100 ml

5. TARGET SPECIES

Pig (pig for fattening).

6. INDICATION(S)

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7. METHOD AND ROUTE(S) OF ADMINISTRATION

Intramuscular use
Read the package leaflet before use

8. WITHDRAWAL PERIODS

Pigs
Meat and offal: 6 days.

9. SPECIAL WARNINGS, IF NECESSARY

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

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only.
This product does not contain an antimicrobial preservative.
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

Laboratorios Support Pharma, S.L.
General Alvarez de Castro, 39
28010 Madrid, Spain

16. MARKETING AUTHORISATION NUMBERS

EU/0/00/000/000

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

Marbofloxacin Support Pharma 40 mg/ml solution for injection for pigs (AT, CY, CZ, DE, EE, EL, ES, IE, IT, LT, LV, PL, PT, SK)
Marbofloxacin 40 mg/ml solution for injection for pigs. (UK)

Marbofloxacin.

2. QUANTITY OF ACTIVE SUBSTANCE

1 ml contains: marbofloxacin 40 mg.

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

50 ml vial

4. ROUTE(S) ADMINISTRATION

Intramuscular use

5. 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

Marbofloxacin Support Pharma 40 mg/ml solution for injection for pigs. (AT, CY, CZ, DE, EE, EL, ES, IE, IT, LT, LV, PL, PT, SK)
Marbofloxacin 40 mg/ml solution for injection for pigs. (UK)

Marbofloxacin.

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

1 ml contains:
Active substance: marbofloxacin 40 mg - **Excipients:** disodium edetate 0.1 mg.

3. PHARMACEUTICAL FORM

Solution for injection.

4. PACKAGE SIZE

100 ml
250 ml

5. TARGET SPECIES

Pig (pig for fattening).

6. INDICATION(S)

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7. METHOD AND ROUTE(S) OF ADMINISTRATION

Intramuscular use
Read the package leaflet before use

8. WITHDRAWAL PERIOD

Pigs
Meat and offal: 6 days.

9. SPECIAL WARNING(S), IF NECESSARY

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

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only.
This product does not contain an antimicrobial preservative.
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

Laboratorios Support Pharma, S.L.
General Alvarez de Castro, 39
28010 Madrid, Spain

16. MARKETING AUTHORISATION NUMBERS

EU/0/00/000/000

17. MANUFACTURER'S BATCH NUMBER

Batch {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

Marbofloxacin Support Pharma 40 mg/ml solution for injection for pigs (AT, CY, CZ, DE, EL, ES, IE, IT, LT, LV, PL, PT, SK)
Marbofloxacin 40 mg/ml solution for injection for pigs. (UK)

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder:

Laboratorios Support Pharma, S.L.
General Alvarez de Castro, 39
28010 Madrid, Spain

Manufacturer responsible for the batch release:

FATRO S.p.A.
Via Emilia, 285
Ozzano Emilia - Bologna
Italy.

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Marbofloxacin Support Pharma 40 mg/ml solution for injection for pigs (AT, CY, CZ, DE, EL, ES, IE, IT, LT, LV, PL, PT, SK)
Marbofloxacin 40 mg/ml solution for injection for pigs. (UK)

Marbofloxacin.

3. STATEMENT OF THE ACTIVE SUBSTANCE AND OTHER INGREDIENTS

1 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 administer to animals known to be hypersensitive to marbofloxacin, other quinolones or to any of the excipients.

6. ADVERSE REACTIONS

Intramuscular administration may cause transient local reactions such as oedema, pain and swelling at the injection site and inflammatory lesions which may persist for 6 days. If you notice any serious effects or other effects not mentioned in this package leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Pig (pig 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 the product/ 10 kg body weight) in a single daily intramuscular injection, for 3-5 consecutive days.

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 the bodyweight and number of animals to be treated**.**

9. ADVICE ON CORRECT ADMINISTRATION

None

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

User warnings

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, lactation or lay

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.

Interaction with other medicinal products and other forms of interaction

None known.

Overdose (symptoms, emergency procedures, antidotes), if necessary

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.
Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

DD/MM/YYYY

15. OTHER INFORMATION

Pack sizes:
50 ml vial
100 ml vial
250 ml vial
6 x 100-ml vials

Not all pack sizes may be marketed.

MA number: EU/0/00/000/000