

Part II
SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

MARBOCYL P 5 mg tablet

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Ingredient

Marbofloxacin 5mg per tablet

For a full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Beige brown spotted round tablet

4. CLINICAL PARTICULARS

4.1 Target species

DOGS AND CATS

4.2 Indications for use, specifying the target species

In dogs

Marbofloxacin is indicated in the treatment of :

- skin and soft tissue infections (skinfold pyoderma, impetigo, folliculitis, furunculosis, cellulitis) caused by susceptible strains of organisms.
- urinary tract infections (UTI) associated or not with prostatitis caused by susceptible strains of organisms.
- respiratory tract infections caused by susceptible strains of organisms.

In cats

Marbofloxacin is indicated in the treatment of skin and soft tissue infections (wounds, abscesses, phlegmons) and upper respiratory tract infections caused by susceptible strains of organisms.

4.3 Contra-indications

Marbofloxacin should not be used in dogs aged less than 12 months, or less than 18 months for exceptionally large breeds of dogs, such as Great Danes, Briard, Bernese, Bouvier and Mastiffs, with a longer growth period. Not recommended for use in cats aged less than 16 weeks.

Not suitable for infections resulting from strict anaerobes, yeast or fungi.

4.4 Special warnings for each target species

Nil

4.5 Special precautions for use

(i) Special precautions for use in animals

The fluoroquinolones have been shown to induce erosion of articular cartilage in juvenile dogs and care should be taken to dose accurately especially in young animals.

The fluoroquinolones are also known for their potential neurological side effects. Cautious use is recommended in dogs and cats diagnosed as suffering from epilepsy.

A low urinary pH could have an inhibitory effect on the activity of marbofloxacin.

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, use of fluoroquinolones should be 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 effectiveness of treatment with other quinolones due to the potential for cross-resistance.

(ii) Special precautions to be taken by the person administering the veterinary medicinal product to animals

People with known hypersensitivity to fluoroquinolones should avoid using this product. In case of accidental ingestion seek medical attention and show product label and/or package leaflet to the doctor. Wear gloves when handling or dividing tablets. Wash hands after use.

4.6 Adverse reactions (frequency and seriousness)

At the therapeutic recommended dosage, no severe side-effects are to be expected in dogs and cats. In particular, no lesions of the articular joints were encountered in clinical studies at the recommended dose rate.

Mild side effects such as vomiting, softening of faeces, modification of thirst or transient increase in activity may occasionally occur. These signs cease spontaneously after treatment and do not necessitate cessation of treatment.

4.7 Use during pregnancy, lactation or lay

Studies in pregnant rats and rabbits showed no side effects on pregnancy. However no specific studies have been carried out in pregnant cats and dogs.

4.8 Interaction with other medicinal products and other forms of interaction

Fluoroquinolones are known to interact with orally administered cations (Aluminium, Calcium, Magnesium, Iron). In such cases, the bioavailability may be reduced.

4.9 Amounts to be administered and administration route

For oral administration.

The recommended dose rate is 2 mg/kg/d (1 tablet for 2.5 kg per day) in single daily administration.

To ensure a correct dosage body weight should be determined as accurately as possible to avoid underdosing.

DOGS:

- in skin and soft tissue infections, treatment duration is at least 5 days. Depending on the course of the disease, it may be extended up to 40 days.
- in urinary tract infections, treatment duration is at least 10 days. Depending on the course of the disease, it may be extended up to 28 days.
- in respiratory infections, treatment duration is at least 7 days and depending on the course of the disease, it may be extended up to 21 days.

CATS:

- for skin and soft tissue infections (wounds, abscesses, phlegmons) treatment duration is 3 to 5 days.
- for upper respiratory infections treatment duration is 5 days.

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

Overdosage may cause acute signs in the form of neurological disorders, which should be treated symptomatically.

4.11 Withdrawal period(s)

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

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 is effective against a wide range of Gram positive bacteria (in particular *Staphylococci*, *Streptococci*) and Gram negative bacteria (*Escherichia coli*, *Salmonella typhimurium*, *Citrobacter freundii*, *Enterobacter cloacae*, *Serratia marcescens*, *Morganella morganii*, *Proteus spp*, *Klebsiella spp*, *Shigella spp*, *Pasteurella spp*, *Haemophilus spp*, *Moraxella spp*, *Pseudomonas spp*, *Brucella canis*) as well as *Mycoplasma spp*.

Marbofloxacin is not active against anaerobes, yeasts or fungi.

Resistance to fluoroquinolones occurs by chromosomal mutation with three mechanisms: decrease of the bacterial wall permeability, expression of the efflux pump or mutation of the enzymes responsible for molecule binding. No significant evolution of resistance to marbofloxacin has been observed in the target pathogenic strains isolated from companion animals since the launch of the molecule on the

veterinary market. The occurrence and rate of transfer of a genetic resistance is therefore considered to be very low.

Cross-resistance with β -lactam antibiotics, aminoglycosides, tetracyclines, macrolide and polypeptide antibiotics, sulfonamides, diaminopyrimidines, and nitrofurans does not generally occur. However, certain mutations conferring resistance to fluoroquinolones can also confer resistance to cephalosporins, tetracyclines, macrolides and chloramphenicol.

5.2 Pharmacokinetic properties :

After oral administration in dogs and cats at the recommended dose of 2 mg/kg, marbofloxacin is readily absorbed and reaches maximal plasma concentrations of 1.5 μ g/ml within 2 hours

Its bioavailability is close to 100%.

It is weakly bound to plasma proteins (less than 10%), extensively distributed and in most tissues (liver, kidney, skin, lung, bladder, digestive tract) it achieves higher concentrations than in plasma. Marbofloxacin is eliminated slowly ($t_{1/2\beta}$ = 14 h in dogs and 10h in cats) predominantly in the active form in urine (2/3) and faeces (1/3).

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose monohydrate
Povidone (K90)
Silica, colloidal anhydrous
Crospovidone (Type A)
Hydrogenated castor oil
Pig liver powder
Yeast powder
Magnesium stearate
Purified water

6.2 Incompatibilities

None known

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years

6.4. Special precautions for storage

No special precautions for storage

6.5 Nature and composition of immediate packaging

Marbofloxacin palatable tablets are packaged in aluminium / aluminium blister packs. Boxes of 10 tablets (1 blister of 10 tablets), 20 tablets (2 blisters of 10 tablets), 30 tablets (3 blisters of 10 tablets), 40 tablets (4 blisters of 10 tablets), 50 tablets (5 blisters of 10 tablets), 100 tablets (10 blisters of 10 tablets), 250 tablets (25 blisters of 10 tablets).

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

7. MARKETING AUTHORISATION HOLDER

Vétoquinol UK Limited
Vetoquinol House
Great Slade
Buckingham Industrial Park
Buckingham
MK18 1PA

8. MARKETING AUTHORISATION NUMBER(S)

Vm 08007/4109

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

20th June 2003/20th June 2008

10. DATE OF REVISION OF THE TEXT

March 2008

Part II
SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

MARBOCYL P 20 mg tablet

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Ingredient

Marbofloxacin 20mg per tablet

For a full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Beige brown spotted round tablet

4. CLINICAL PARTICULARS

4.1 Target species

DOGS

4.2 Indications for use, specifying the target species

Marbofloxacin is indicated in the treatment of :

- skin and soft tissue infections (skinfold pyoderma, impetigo, folliculitis, furunculosis, cellulitis) caused by susceptible strains of organisms.
- urinary tract infections (UTI) associated or not with prostatitis caused by susceptible strains of organisms.
- respiratory tract infections caused by susceptible strains of organisms.

4.3 Contra-indications

Marbofloxacin should not be used in dogs aged less than 12 months, or less than 18 months for exceptionally large breeds of dogs, such as Great Danes, Briard, Bernese Bonvier and Mastiffs, with a longer growth period.

Not suitable for infections resulting from strict anaerobes, yeast or fungi.

Do not use in cats. For the treatment of this species, a 5 mg tablet is available.

4.4 Special warnings for each target species

Nil

4.5 Special precautions for use

(i) Special precautions for use in animals

The fluoroquinolones have been shown to induce erosion of articular cartilage in juvenile dogs and care should be taken to dose accurately especially in young animals.

The fluoroquinolones are also known for their potential neurological side effects. Cautious use is recommended in dogs and cats diagnosed as suffering from epilepsy.

A low urinary pH could have an inhibitory effect on the activity of marbofloxacin.

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, use of fluoroquinolones should be 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 effectiveness of treatment with other quinolones due to the potential for cross-resistance.

(ii) Special precautions to be taken by the person administering the veterinary medicinal product to animals

People with known hypersensitivity to fluoroquinolones should avoid using this product.

In case of accidental ingestion seek medical attention and show product label and/or package leaflet to the doctor. Wear gloves when handling or dividing tablets. Wash hands after use.

4.6 Adverse reactions (frequency and seriousness)

At the therapeutic recommended dosage, no severe side-effects are to be expected in dogs and cats. In particular, no lesions of the articular joints were encountered in clinical studies at the recommended dose rate.

Mild side effects such as vomiting, softening of faeces, modification of thirst or transient increase in activity may occasionally occur. These signs cease spontaneously after treatment and do not necessitate cessation of treatment.

4.7 Use during pregnancy, lactation or lay

Studies in pregnant rats and rabbits showed no side effects on pregnancy. However no specific studies have been carried out in pregnant dogs.

4.8 Interaction with other medicinal products and other forms of interaction

Fluoroquinolones are known to interact with orally administered cations (Aluminium, Calcium, Magnesium, Iron). In such cases, the bioavailability may be reduced.

4.9 Amounts to be administered and administration route

For oral administration.

The recommended dose rate is 2 mg/kg/d (1 tablet for 10 kg per day) in single daily administration. To ensure a correct dosage body weight should be determined as accurately as possible to avoid underdosing.

- in skin and soft tissue infections, treatment duration is at least 5 days. Depending on the course of the disease, it may be extended up to 40 days.
- in urinary tract infections, treatment duration is at least 10 days. Depending on the course of the disease, it may be extended up to 28 days.
- in respiratory infections, treatment duration is at least 7 days and depending on the course of the disease, it may be extended up to 21 days.

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

Overdosage may cause acute signs in the form of neurological disorders, which should be treated symptomatically.

4.11 Withdrawal period(s)

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

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 is effective against a wide range of Gram positive bacteria (in particular *Staphylococci*, *Streptococci*) and Gram negative bacteria (*Escherichia coli*, *Salmonella typhimurium*, *Citrobacter freundii*, *Enterobacter cloacae*, *Serratia marcescens*, *Morganella morganii*, *Proteus spp*, *Klebsiella spp*, *Shigella spp*, *Pasteurella spp*, *Haemophilus spp*, *Moraxella spp*, *Pseudomonas spp*, *Brucella canis*) as well as *Mycoplasma spp*.

Marbofloxacin is not active against anaerobes, yeasts or fungi.

Resistance to fluoroquinolones occurs by chromosomal mutation with three mechanisms: decrease of the bacterial wall permeability, expression of the efflux pump or mutation of the enzymes responsible for molecule binding. No significant evolution of resistance to marbofloxacin has been observed in the target pathogenic strains isolated from companion animals since the launch of the molecule on the veterinary market. The occurrence and rate of transfer of a genetic resistance is therefore considered to be very low.

Cross-resistance with β -lactam antibiotics, aminoglycosides, tetracyclines, macrolide and polypeptide antibiotics, sulfonamides, diaminopyrimidines, and nitrofurans does not generally occur. However, certain mutations conferring resistance to fluoroquinolones can also confer resistance to cephalosporins, tetracyclines, macrolides and chloramphenicol

5.2 Pharmacokinetic properties :

After oral administration in dogs and cats at the recommended dose of 2 mg/kg, marbofloxacin is readily absorbed and reaches maximal plasma concentrations of 1.5 μ g/ml within 2 hours

Its bioavailability is close to 100%.

It is weakly bound to plasma proteins (less than 10%), extensively distributed and in most tissues (liver, kidney, skin, lung, bladder, digestive tract) it achieves higher concentrations than in plasma. Marbofloxacin is eliminated slowly ($t_{1/2\beta} = 14$ h) predominantly in the active form in urine (2/3) and faeces (1/3).

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose monohydrate
Povidone (K90)
Silica, colloidal anhydrous
Crospovidone (Type A)
Hydrogenated castor oil
Pig liver powder
Yeast powder
Magnesium stearate
Purified water

6.2 Incompatibilities

None known

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years

6.4. Special precautions for storage

No special precautions for storage

6.4 Nature and composition of immediate packaging

Marbofloxacin palatable tablets are packaged in aluminium / aluminium blister packs. Boxes of 10 tablets (1 blister of 10 tablets), 20 tablets (2 blisters of 10 tablets), 30 tablets (3 blisters of 10 tablets), 40 tablets (4 blisters of 10 tablets), 50 tablets (5 blisters of 10 tablets), 100 tablets (10 blisters of 10 tablets), 250 tablets (25 blisters of 10 tablets).

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

7. MARKETING AUTHORISATION HOLDER

Vétoquinol UK Limited
Vetoquinol House
Great Slade
Buckingham Industrial Park
Buckingham
MK18 1PA

8. MARKETING AUTHORISATION NUMBER(S)

Vm 08007/4110

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

20th June 2003/20th June 2008

10. DATE OF REVISION OF THE TEXT

March 2008

Part II
SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

MARBOCYL P 80 mg tablet

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Ingredient

Marbofloxacin 80mg per tablet

For a full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Beige brown spotted round tablet

4. CLINICAL PARTICULARS

4.1 Target species

DOGS

4.2 Indications for use, specifying the target species

Marbofloxacin is indicated in the treatment of :

- skin and soft tissue infections (skinfold pyoderma, impetigo, folliculitis, furunculosis, cellulitis) caused by susceptible strains of organisms.
- urinary tract infections (UTI) associated or not with prostatitis caused by susceptible strains of organisms.
- respiratory tract infections caused by susceptible strains of organisms.

4.3 Contra-indications

Marbofloxacin should not be used in dogs aged less than 12 months, or less than 18 months for exceptionally large breeds of dogs, such as Great Danes, Briard, Bernese Bonvier and Mastiffs, with a longer growth period.

Not suitable for infections resulting from strict anaerobes, yeast or fungi.

Do not use in cats. For the treatment of this species, a 5 mg tablet is available.

4.4 Special warnings for each target species

Nil

4.5 Special precautions for use

(i) Special precautions for use in animals

The fluoroquinolones have been shown to induce erosion of articular cartilage in juvenile dogs and care should be taken to dose accurately especially in young animals.

The fluoroquinolones are also known for their potential neurological side effects. Cautious use is recommended in dogs and cats diagnosed as suffering from epilepsy.

A low urinary pH could have an inhibitory effect on the activity of marbofloxacin.

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, use of fluoroquinolones should be 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 effectiveness of treatment with other quinolones due to the potential for cross-resistance.

(ii) Special precautions to be taken by the person administering the veterinary medicinal product to animals

People with known hypersensitivity to fluoroquinolones should avoid using this product.

In case of accidental ingestion seek medical attention and show product label and/or package leaflet to the doctor. Wear gloves when handling or dividing tablets. Wash hands after use.

4.6 Adverse reactions (frequency and seriousness)

At the therapeutic recommended dosage, no severe side-effects are to be expected in dogs and cats. In particular, no lesions of the articular joints were encountered in clinical studies at the recommended dose rate.

Mild side effects such as vomiting, softening of faeces, modification of thirst or transient increase in activity may occasionally occur. These signs cease spontaneously after treatment and do not necessitate cessation of treatment.

4.7 Use during pregnancy, lactation or lay

Studies in pregnant rats and rabbits showed no side effects on pregnancy. However no specific studies have been carried out in pregnant dogs.

4.8 Interaction with other medicinal products and other forms of interaction

Fluoroquinolones are known to interact with orally administered cations (Aluminium, Calcium, Magnesium, Iron). In such cases, the bioavailability may be reduced.

4.9 Amounts to be administered and administration route

For oral administration.

The recommended dose rate is 2 mg/kg/d (1 tablet for 40 kg per day) in single daily administration. To ensure a correct dosage body weight should be determined as accurately as possible to avoid underdosing.

- in skin and soft tissue infections, treatment duration is at least 5 days. Depending on the course of the disease, it may be extended up to 40 days.
- in urinary tract infections, treatment duration is at least 10 days. Depending on the course of the disease, it may be extended up to 28 days.
- in respiratory infections, treatment duration is at least 7 days and depending on the course of the disease, it may be extended up to 21 days.

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

Overdosage may cause acute signs in the form of neurological disorders, which should be treated symptomatically.

4.11 **Withdrawal period(s)**

Not applicable.

5. **PHARMACOLOGICAL PROPERTIES**

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 is effective against a wide range of Gram positive bacteria (in particular *Staphylococci*, *Streptococci*) and Gram negative bacteria (*Escherichia coli*, *Salmonella typhimurium*, *Citrobacter freundii*, *Enterobacter cloacae*, *Serratia marcescens*, *Morganella morganii*, *Proteus spp*, *Klebsiella spp*, *Shigella spp*, *Pasteurella spp*, *Haemophilus spp*, *Moraxella spp*, *Pseudomonas spp*, *Brucella canis*) as well as *Mycoplasma spp*.

Marbofloxacin is not active against anaerobes, yeasts or fungi.

Resistance to fluoroquinolones occurs by chromosomal mutation with three mechanisms: decrease of the bacterial wall permeability, expression of the efflux pump or mutation of the enzymes responsible for molecule binding. No significant evolution of resistance to marbofloxacin has been observed in the target pathogenic strains isolated from companion animals since the launch of the molecule on the veterinary market. The occurrence and rate of transfer of a genetic resistance is therefore considered to be very low.

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5.2 Pharmacokinetic properties :

After oral administration in dogs and cats at the recommended dose of 2 mg/kg, marbofloxacin is readily absorbed and reaches maximal plasma concentrations of 1.5 μ g/ml within 2 hours

Its bioavailability is close to 100%.

It is weakly bound to plasma proteins (less than 10%), extensively distributed and in most tissues (liver, kidney, skin, lung, bladder, digestive tract) it achieves higher concentrations than in plasma. Marbofloxacin is eliminated slowly ($t_{1/2\beta} = 14$ h) predominantly in the active form in urine (2/3) and faeces (1/3).

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose monohydrate
Povidone (K90)
Silica, colloidal anhydrous
Crospovidone (Type A)
Hydrogenated castor oil
Pig liver powder
Yeast powder
Magnesium stearate
Purified water

6.2 Incompatibilities

None known

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years

6.4. Special precautions for storage

No special precautions for storage.

6.4 Nature and composition of immediate packaging

Marbofloxacin tablets are packaged in aluminium / aluminium blister packs. Boxes of 6 to 480 tablets (boxes containing 1 blister of 6 tablets to 80 blisters of 6 tablets).

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

7. MARKETING AUTHORISATION HOLDER

Vétoquinol UK Limited
Vetoquinol House
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Buckingham Industrial Park
Buckingham
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8. MARKETING AUTHORISATION NUMBER(S)

Vm 08007/4111

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

20th June 2003/20th June 2008

10. DATE OF REVISION OF THE TEXT

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