PARTICULARS TO APPEAR ON THE OUTER PACKAGE - CARTON

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

MARBOCYL P 5 mg tablet

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Marbofloxacin 5 mg per tablet

3. PHARMACEUTICAL FORM

Tablet

4. PACKAGE SIZE

Carton contains 100 tablets
Boxes of 10 tablets (1 blister of 10 tablets)
Boxes of 20 tablets (2 blisters of 10 tablets)
Boxes of 30 tablets (3 blisters of 10 tablets)
Boxes of 40 tablets (4 blisters of 10 tablets)
Boxes of 50 tablets (5 blisters of 10 tablets)
Boxes of 100 tablets (10 blisters of 10 tablets)
Boxes of 250 tablets (25 blisters of 10 tablets)

5. TARGET SPECIES

Dog and cat

6. INDICATION(S)

Infections caused by susceptible strains of organisms.

In dogs:
Marbocyl® P is indicated in the treatment of:
Skin and soft tissue infections (skinfold pyoderma, impetigo, folliculitis, furunculosis, cellulitis).
Urinary tract infections (UTI) associated or not with prostatitis. Respiratory tract infections.

In cats:
Marbocyl® P is indicated in the treatment of:
Skin and soft tissue infections (wounds, abscesses). Upper respiratory tract infections.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

The recommended dose rate is 2mg/kg/day (1 tablet for 2.5kg per day) by single daily oral 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), treatment duration is 3 to 5 days. For upper respiratory infections treatment duration is 5 days.

8. WITHDRAWAL

9. SPECIAL WARNING(S), IF NECESSARY

Operator Warnings See package leaflet

Contra-indications and warnings
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, Briards, Bernese Bouviers and Mastiffs, with a longer growth period.

Not recommended for use in cats aged less than 16 weeks.

Do not use in cases of hypersensitivity to fluoroquinolones or any of the excipients of the product.
Do not use in cases of resistance against quinolones since (almost) complete cross-resistance exists against other fluoroquinolones.

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

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. However, joint pain and/or neurological symptoms (ataxia, aggression, convulsion, depression) may occur on rare occasions.

Allergic reactions have been observed (temporary skin reactions) due to histamine release that may occur.

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.

The frequency of adverse reactions is defined using the following convention:
- rare (more than 1 but less than 10 animals in 10,000 animals treated)

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.

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

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

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.

User Information
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.

10. EXPIRY DATE

Exp.

11. SPECIAL STORAGE CONDITIONS

No special precautions for storage

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

Dispose of used packaging in the household refuse.
Unused tablets including halved tablets should be returned to the veterinary surgeon.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

[Distribution category]

For animal treatment only

POM-V

To be supplied only on veterinary prescription

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

Keep out of reach of children

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Vetoquinol UK Limited
Steadings Barn
Pury Hill Business Park
Nr. Alderton
Towcester
Northamptonshire
NN12 7LS

16. MARKETING AUTHORISATION NUMBER

Vm 08007/4109

17. MANUFACTURER'S BATCH NUMBER

Lot.

PACKAGE LEAFLET FOR: Marbocyl P

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

Vetoquinol UK Limited
Steadings Barn
Pury Hill Business Park
Nr. Alderton
Towcester
Northamptonshire
NN12 7LS

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Marbocyl P 5 mg
Marbocyl P 20 mg
Marbocyl P 80 mg

3. STATEMENT OF THE ACTIVE SUBSTANCE (S) AND OTHER INGREDIENTS

Marbocyl P 5mg
Divisible tablets containing 5 mg of marbofloxacin
MARBOCYL ®P 5 mg : Vm 08007/4109
Blisters of 10 tablets for MARBOCYL®P 5 mg
Marbocyl P 20mg
Divisible tablets containing 20 mg of marbofloxacin
MARBOCYL®P 20 mg : Vm 08007/4110
Blisters of 10 tablets for MARBOCYL®P 20 mg
Marbocyl P 80mg
Divisible tablets containing 80 mg of marbofloxacin
MARBOCYL®P 80 mg : Vm 08007/4111
Blisters of 6 tablets for MARBOCYL®P 80 mg

4. INDICATION(S)

Infections caused by susceptible strains of organisms.
IN DOGS: Marbocyl® P is indicated in the treatment of:
Skin and soft tissue infections (skinfold pyoderma, impetigo, folliculitis, furunculosis, cellulitis).
Urinary tract infections (UTI) associated or not with prostatitis.
Respiratory tract infections.
In CATS: Marbocyl® P is indicated in the treatment of:
Skin and soft tissue infections (wounds, abscesses).
Upper respiratory tract infections.

5. CONTRAINDICATIONS

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, Briards, Bernese Bouviers and Mastiffs, with a longer growth period. Not recommended for use in cats aged less than 16 weeks.

Do not use in cases of hypersensitivity to fluoroquinolones or any of the excipients of the product.

Do not use in cases of resistance against quinolones since (almost) complete cross-resistance exists against other fluoroquinolones.

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

6. ADVERSE REACTIONS

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. However, joint pain and/or neurological symptoms (ataxia, aggression, convulsion, depression) may occur on rare occasions.

Allergic reactions have been observed (temporary skin reactions) due to histamine release that may occur.

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.

The frequency of adverse reactions is defined using the following convention:
- rare (more than 1 but less than 10 animals in 10,000 animals treated)

7. TARGET SPECIES

Cats and Dogs

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

- Recommended dose rate:

To ensure a correct dosage body weight should be determined as accurately as possible to avoid underdosing.
2 mg/kg/day in dogs and cats in a single daily administration by oral route. The daily dose is achieved as follows:
Cats and small dogs : MARBOCYL®P 5 mg - 1 tablet per 2.5 kg bw Medium dogs : MARBOCYL®P 20 mg - 1 tablet per 10 kg bw Large dogs : MARBOCYL®P 80 mg - 1 tablet per 40 kg bw

• Duration of treatment:

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

9. ADVICE ON CORRECT ADMINISTRATION

See section 8.

10. WITHDRAWAL PERIOD(S)

11. SPECIAL STORAGE PRECAUTIONS

No special precautions for storage

12. SPECIAL WARNING(S)

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 are known to interact with orally administered cations (Aluminium, Calcium, Magnesium, Iron). In such cases, the bioavailability may be reduced. Overdosage may cause acute signs in the form of neurological disorders, which should be treated symptomatically.

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, 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.

OPERATOR WARNINGS
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. Do not use Marbocyl® P 20 mg or Marbocyl® P 80 mg tablets in cats. For the treatment of this species the 5 mg tablet should be used.
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.

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

Dispose of used packaging in the household refuse. Unused tablets including halved tablets should be returned to the veterinary surgeon.

Marbocyl® P palatable tablets are packaged in aluminium /aluminium blister packs.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

September 2023

15. OTHER INFORMATION

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.
USES
Pharmacodynamic properties: Marbofloxacin is a synthetic, bactericidal antimicrobial, belonging to the fluoroquinolone group which acts by inhibition of the 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.*
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 µg/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 (t1/2ß=12-14 h in dogs and 8-10 h in cats) predominantly in the active form in urine (2/3) and faeces (1/3)
For animal treatment only

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS (Dispensing carton)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Marbocyl P Tablets

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Marbofloxacin Antibiotic

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

Tablets dispensed
Marbocyl P 5 mg □ 20 mg □ 80 mg □

4. PHARMACEUTICAL FORM

Tablet

6. SPECIAL STORAGE PRECAUTIONS

Keep out of reach of children
No special precautions for storage

7. SPECIAL WARNINGS

People with known hypersensitivity to fluoroquinolones should avoid using the 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.

8. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

[Distribution category]

POM-V

For animal treatment only
To be supplied only on veterinary prescription

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

Keep out of reach of children

10. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Vetoquinol UK Limited
Steadings Barn
Pury Hill Business Park
Nr. Alderton
Towcester
Northamptonshire
NN12 7LS

11. MARKETING AUTHORISATION NUMBER(S)

MARBOCYL®P 5 mg tablets : VM 08007/4109
MARBOCYL®P 20 mg tablets : VM 08007/4110
MARBOCYL®P 80 mg tablets : VM 08007/4111

12. OTHER INFORMATION

Prescribed by: Veterinary Surgeon’s name and address

MINIMUM PARTICULARS TO APPEAR ON BLISTERS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Marbocyl P 5 mg Marbofloxacin

2. TARGET SPECIES

Dogs and Cats

3. PHARMACEUTICAL FORM

Palatable tablets

4. NAME OF THE MARKETING AUTHORISATION HOLDER

Vetoquinol

5. EXPIRY DATE

6. BATCH NUMBER

7. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only

Approved 29 September 2023