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Date: Tuesday, February 17, 2026 15:50

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Marbocyl P 5mg, 20mg and 80mg Tablets

Species: Cats, Dogs

Therapeutic indication: Pharmaceuticals: Antimicrobials: Oral preparations: Tablets

Active ingredient: Marbofloxacin

Product: Marbocyl™ P 5mg, 20mg and 80 mg Tablets

Product index: Marbocyl P Tablets

Incorporating:

Presentation

Beige brown spotted round tablets

Three strengths are available.

Marbocyl P 5 mg containing 5 mg marbofloxacin. For use in dogs and cats.

Marbocyl P 20 mg containing 20 mg marbofloxacin. For use in dogs.

Marbocyl P 80 mg containing 80 mg marbofloxacin. For use in dogs.

Uses

In Dogs

Marbocyl is indicated in the treatment of skin and soft tissue infections (skin fold pyoderma, impetigo, folliculitis, furunculosis, cellulitis), for the treatment of urinary tract infections associated or not with prostatitis and respiratory tract infections, caused by susceptible strains of organisms.

In Cats (Marbocyl P 5mg Tablet only)

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

Dosage and administration

For oral administration.

The recommended dose rate is 2 mg/kg per day in a 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 five 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, may be extended up to 21 days.

CATS

- For the treatment of skin and soft tissue infections, treatment duration is 3–5 days.
- For upper respiratory infections, treatment duration is 5 days.

Contra-indications, warnings, etc

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.

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

Do not use in the 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.

Do not use Marbocyl P 20mg or Marbocyl P 80mg tablets in cats. For the treatment of this species, the Marbocyl P 5mg tablet is available.

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 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.

Adverse reactions (frequency and seriousness)

At the therapeutic recommended dosage no severe side effects are to be expected in cats and dogs. 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 the treatment.

The frequency of adverse reactions is defined using the following convention:

- rare (more than 1 but less than 10 animals in 10,000 treated)

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.

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.

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

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

Withdrawal period(s)

Not applicable

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.

Pharmaceutical precautions

No special precautions for storage.

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

Legal category

Legal category:POM-V

Packaging quantities

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

Marbocyl P 5mg 10 blisters of 10 tablets

Marbocyl P 20mg 10 blisters of 10 tablets

Marbocyl P 80mg 12 blisters of 6 tablets

Further information

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 effective 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.

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 (<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 ($t_{1/2\beta} = 14\text{h}$ in dogs and 10h in cats) predominately in the active form, in urine (2/3) and faeces (1/3).

Marketing Authorisation Number

Marbocyl P 5 mg

UK (GB): Vm 08007/5024

UK (NI): Vm 06462/3015

Marbocyl P 20 mg

UK (GB): Vm 08007/5023

UK (NI): Vm 06462/3014

Marbocyl P 80 mg

UK (GB): Vm 08007/5025

UK (NI): Vm 06462/3016

Significant changes

GTIN

GTIN description:Marbocyl P 5mg

GTIN:03605877310220

GTIN description:Marbocyl P 20mg

GTIN:03605877310312

GTIN description:Marbocyl P 80mg

GTIN:03605877310497