

# Marbocyl P 5mg, 20mg and 80mg Tablets

## Introduction



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## Presentation

### 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 for 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

The recommended dose rate is 2 mg/kg per day in a single daily administration.

In dogs for the treatment of 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.

In 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.

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

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.

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.

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

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.

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.

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.

### *Withdrawal periods*

Not applicable

### *Operator warning*

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

Store below 25°C and protect from light.

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

POM-V (previously POM)

## Packaging Quantities

Marbofloxacin palatable 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

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.

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

## Marketing authorisation number

Marbocyl P 5 mg Vm08007/4109.

Marbocyl P 20 mg Vm08007/4110.

Marbocyl P 80 mg Vm08007/4111.