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.

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.

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 the 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. 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)

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.

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 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 (t½ß = 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 caster oil
Pig liver powder
Yeast powder
Magnesium stearate
Purified water

6.2 Incompatibilities

None known

6.3 Shelf life

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

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

8. MARKETING AUTHORISATION NUMBER

Vm 08007/5023

9. DATE OF FIRST AUTHORISATION

20 June 2003

10. DATE OF REVISION OF THE TEXT

July 2025

Gavin Hall
Approved: 31 July 2025