SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Marbocyl P 20 mg tablet for dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

Active substance:

Marbofloxacin 20mg

Excipients:

Qualitative composition of excipients and other constituents
Lactose monohydrate
Povidone (K90)
Silica, colloidal anhydrous
Crospovidone (Type A)
Hydrogenated caster oil
Pig liver powder
Yeast powder
Magnesium stearate
Purified water

Beige brown spotted round tablet.

3. CLINICAL INFORMATION

3.1 Target species

Dogs.

3.2 Indications for use for each 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.

3.3 Contraindications

Do not use 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.

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

Do not use 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.

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:

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.

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.

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 the package leaflet or the label to the physician. Wear gloves when handling or dividing tablets. Wash hands after use.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Dogs:

Rare (1 to 10 animals / 10,000 animals treated):	Joint pain Neurological disorder (ataxia, seizure) Depression Aggression
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Allergic skin reaction[1,2] Vomiting[3,4], loose stool[3,4] Excessive thirst[3,4] Hyperactivity[2,3,4]

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.
[1] Due to histamine release
[2] Transient
[3] Mild
[4] These signs cease spontaneously after treatment and do not necessitate cessation of treatment

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 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.

3.8 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.

3.9 Administration routes and dosage

To ensure a correct dosage, body weight should be determined as accurately as possible.

For oral administration.

The recommended dose rate is 2 mg/kg/d (1 tablet for 10 kg per day) in single daily administration.

- 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.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

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

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Not applicable.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QJ01MA93

4.2 Pharmacodynamics

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.

4.3 Pharmacokinetics

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).

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Not applicable.

5.2 Shelf life

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

5.3 Special precautions for storage

This veterinary medicinal product does not require any special storage conditions.

5.4 Nature and composition of immediate packaging

Aluminium / aluminium blister strips containing 10 tablets/blister.
Cardboard box:
Pack sizes of 10, 20, 30, 40, 50, 100 and 250 tablets.
Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Vetoquinol SA

7. MARKETING AUTHORISATION NUMBER

Vm 06462/3014

8. DATE OF FIRST AUTHORISATION

20 June 2003

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

April 2026

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT

Veterinary medicinal product subject to prescription.

Find more product information by searching for the ‘Product Information Database’ on www.gov.uk.