1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Marbocyl P 80 mg Tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

Active substance:

Marbofloxacin 80 mg

Excipients:

Qualitative composition of excipients and other constituents
Lactose Monohydrate
Povidone
Crospovidone
Liver Powder
Yeast powder
Silica, colloidal anhydrous
Hydrogenated Castor Oil
Magnesium Stearate

Brown-beige spotted, circular divisible tablets.

3. CLINICAL INFORMATION

3.1 Target species

Dogs.

3.2 Indications for use for each target species

The veterinary medicinal product is indicated in the treatment of:

Skin and soft tissue infections (intertrigo, folliculitis, impetigo, furunculosis, cellulitis) caused by susceptible strains.
Lower and upper urinary tract infections (UTI) associated or not with prostatitis or epididymitis caused by susceptible strains.
Respiratory tract infections caused by susceptible strains.

3.3 Contraindications

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.
Do not use in dogs aged less than 12 months, or less than 18 months for giant breeds of dogs.

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:

Not applicable.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

Not applicable.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Dogs:

Very rare (<1 animal / 10 000 animals treated, including isolated reports):	Hypersensitivity (allergic reaction) Vomiting[1,3], loose stool[1,3] Polydipsia[1,3,] adipsia [1,3] Hyperactivity[1,2,3] Joint cartilage disorder[4] (erosion[4])

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

At the therapeutic recommended dosage, no severe side-effects are to be expected in dogs.
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 its local representative 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

Pregnancy and lactation:

Can be used during pregnancy and lactation.

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

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

The recommended dose rate is 2 mg/kg/d (1 tablet for 40 kg per day) in a single daily administration.

In skin and soft tissue infections, treatment duration is at least 5 days. Depending on clinical evolution, it may be extended up to 40 days.
In lower urinary tract infections, treatment duration is at least 10 days.
In case of associated prostatitis or epididymitis or in case of upper urinary tract infections, treatment 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)

Overdose may cause acute signs in the form of neurological disorders which would have to 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.

4.3 Pharmacokinetics

After oral administration 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 precautions.

5.4 Nature and composition of immediate packaging

Aluminium / aluminium blister strips containing 6 tablets/blister.
Cardboard box:
Pack sizes of 6 to 480 tablets (boxes containing 1 blister of 6 tablets to 80 blisters of 6 tablets).
Not all pack sizes may be marketed.

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

Medicines should not be disposed of via wastewater or household waste.

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 S.A.

7. MARKETING AUTHORISATION NUMBER(S)

VPA10521/031/003

8. DATE OF FIRST AUTHORISATION

19/04/2004

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

19/06/2026

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).