SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Quiflor 80 mg tablets for dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

Active substances:
Marbofloxacin…….80 mg

Excipients:

Qualitative composition of excipients and other constituents
Lactose monohydrate
Povidone (K 90)
Yeast powder
Meat flavour
Crospovidone
Castor oil, hydrogenated
Silica, Colloidal Anhydrous
Magnesium stearate

Light brownish yellow, capsule shaped, biconvex, marble tablets with possible dark and white spots and scored on the both sides.
The tablets can be divided into halves.

3. CLINICAL INFORMATION

3.1 Target species

Dogs.

3.2 Indications for use for each target species

Treatment of infections caused by strains of microorganisms susceptible to marbofloxacin in dogs:
- skin and soft tissue infections (skinfold pyoderma, impetigo, folliculitis, furunculosis, cellulitis);
- urinary tract infections (UTI) associated or not with prostatitis or epididymitis;
- respiratory tract infections.

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, Bouvier and Mastiffs, with a longer growth period.
Do not use in cats. For the treatment of this species, a 5 mg tablet is available.

Do not use in cases of hypersensitivity to marbofloxacin or other (fluoro)quinolones or to any of the excipients.
Do not use in cases of resistance against quinolones, since (almost) complete cross-resistance exists against other fluoroquinolones.

3.4 Special warnings

A low urinary pH could have an inhibitory effect on the activity of marbofloxacin.
Pyoderma occurs mostly secondary to an underlying disease, thus, it is advisable to determine the underlying cause and to treat the animal accordingly.

3.5 Special precautions for use

Special precautions for safe use in the target species:

High doses of some fluoroquinolones may have epileptogenic potential. Cautious use is recommended in dogs diagnosed as suffering from epilepsy. However, at the therapeutic recommended dosage, no severe side-effects are to be expected in dogs. 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 recommended dose rate, no lesions of the articular joints were encountered in clinical studies.

Official and local antimicrobial policies should be taken in to account when the veterinary medicinal product is used. 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 (fluoro)quinolones and may decrease 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 (fluoro)quinolones should avoid contact with the veterinary medicinal product.
In case of accidental ingestion seek medical advice immediately and show the package leaflet or the label to the physician.
Wash hands after use.

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):	Vomiting[1], soft faeces[1] Modification of thirst[1] Hyperactivity[1,2]

[1]Ceases spontaneously after treatment and do not necessitate cessation of treatment.
[2]Transient.

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

Pregnancy and lactation:

Studies in laboratory animals (rat, rabbit) showed no embryotoxicity, teratogenicity and maternotoxicity with marbofloxacin at therapeutic doses.

The safety of the veterinary medicinal product has not been established during pregnancy and lactation.
Use only according to the benefit-risk assessment by the responsible veterinarian.

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 of marbofloxacin may be reduced. Concurrent administration of theophylline products may be followed by inhibited theophylline clearance.

3.9 Administration routes and dosage

For oral administration.

The recommended dose rate is 2 mg marbofloxacin/kg body weight/day (1 tablet for 40 kg body weight per day) in single daily administration. Where appropriate, the use of combinations of whole or half tablets of different strengths (80 mg, 20 mg or 5 mg) will allow accurate dosing :

Animal body weight (kg)	Number of tablets **(80 mg + 20 mg strengths)**	Approx. dosage range (mg/kg)
17 – 20	0.5	2.0 – 2.4
>20 – 25	0.5 + 0.5	2.0 – 2.5
>25 – 30	0.5 + 1	2.0 – 2.4
>30 – 40	1	2.0 – 2.7
>40 – 50	1 + 1	2.0 – 2.5
>50	1.5	≤2.4

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

Duration of treatment:
- for skin and soft tissue infections, treatment duration is at least 5 days and depending on the course of the disease, it may be extended up to 40 days;
- for urinary tract infections, treatment duration is at least 10 days and depending on the course of the disease, it may be extended up to 28 days;
- for 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 and of topoisomerase IV. It is effective against a wide range of Gram-positive bacteria (including streptococci and in particular staphylococci,) and Gram-negative bacteria (*Escherichia coli, Citrobacter freundii, Proteus* spp., *Klebsiella* spp., *Shigella* spp., *Pasteurella* spp., *Pseudomonas* spp.) as well as *Mycoplasma* spp.
A secondary literature report of microbiological susceptibility data whose source included two European field surveys, each involving hundreds of canine and feline pathogens susceptible to marbofloxacin, was published in 2014.

Microorganism	MIC_{50} (µg/ml)
Staphylococcus intermedius	0.250
Escherichia coli	0.030
Pasteurella multocida	0.030
Pseudomonas aeruginosa	0.500

Susceptibility break points have been determined as ≤1 µg/ml for sensitive, 2 µg/ml for intermediate and ≥4 µg/ml for resistant bacterial strains.

Marbofloxacin is not active against anaerobes, yeast or fungi. Cases of resistance have been observed in *Streptococcus*.
Resistance to fluoroquinolones occurs by chromosomal mutations leading to decrease of the bacterial cell wall permeability, expression change of efflux pumps or changes of primary structure of target enzymes responsible for molecule binding. In some Gram-negative bacteria, plasmid-mediated quinolone resistance has been reported.

4.3 Pharmacokinetics

After oral administration in dogs at the recommended dose of 2 mg/kg body weight, 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 in dogs) 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.
Shelf life of half-tablets: 5 days.

5.3 Special precautions for storage

Store in the original package in order to protect from light.
This veterinary medicinal product does not require any special temperature storage conditions.

5.4 Nature and composition of immediate packaging

Polyvinylchloride-aluminium-oriented polyamide/Aluminium cold formed blister.
Pack sizes:
Cardboard box containing 2 blisters of 6 tablets.
Cardboard box containing 12 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.

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

KRKA, d.d., Novo mesto

7. MARKETING AUTHORISATION NUMBER

Vm 01656/4046

8. DATE OF FIRST AUTHORISATION

25 April 2013

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

August 2025

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

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

Approved 25 November 2025
Gavin Hall