ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

{CARDBOARD BOX}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Marfloquin 20 mg tablets (AT, BE, DE, ES, FR, UK (NI), NL, PT)
Quiflor 20 mg tablets (EL)

2. STATEMENT OF ACTIVE SUBSTANCES

Each tablet contains 20 mg of marbofloxacin.

3. PACKAGE SIZE

10 tablets
100 tablets

4. TARGET SPECIES

Dogs

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Oral use.
The tablets can be divided into halves.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}

Shelf life of half-tablets: 5 days.

9. SPECIAL STORAGE PRECAUTIONS

Store in the original package in order to protect from light.

10. THE WORDS "READ THE PACKAGE LEAFLET BEFORE USE"

Read the package leaflet before use.

11. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

12. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

KRKA, d.d., Novo mesto

14. MARKETING AUTHORISATION NUMBERS

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

{BLISTER}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Marfloquin (AT, BE, DE, ES, FR, UK (NI), NL, PT)
Quiflor (EL)

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

20 mg

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Marfloquin 20 mg tablets for dogs (AT, BE, DE, ES, FR, UK (NI), NL, PT)
Quiflor 20 mg tablets for dogs (EL)

2. Composition

Each tablet contains:

Active substances:
Marbofloxacin ……..20 mg

Light brownish yellow, round, biconvex, marble tablets with bevelled edges and with possible dark and white spots, scored on one side.
The tablets can be divided into halves.

3. Target species

Dogs

4. Indications for use

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.

5. 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.

6. Special warnings

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.

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.

Pregnancy and lactation:
The safety of the veterinary medicinal product has not been established during pregnancy and lactation in dogs.

Laboratory studies in rats and rabbits have not produced any evidence of foetotoxic, teratogenic and maternotoxic effects with marbofloxacin at therapeutic doses.

Use only according to the benefit-risk assessment by the responsible veterinarian.

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.

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

7. 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 product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or its local representative using the contact details at the end of this leaflet, or via your national reporting system:

8. Dosage for each species, routes and method of administration

Oral use.

The recommended dose rate is 2 mg/kg/day (1 tablet for 10 kg per day) in single daily administration. Where appropriate, the use of combinations of whole or half tablets of different strengths (5 mg, 20 mg or 80 mg) will allow accurate dosing.

Animal body weight (kg)	Number of tablets **(20 mg + 5 mg strengths)**	Approx. dosage range (mg/kg)
4 – 6	0.5 + 0.5	2.1 – 3.1
>6 – 9	1	2.0 – 3.3
>9 – 11	1 + 1	2.3 – 2.8
>11 – 15	1.5	2.0 – 2.7
>15 – 20	2	2.0 – 2.7
>20 – 25	2.5	2.0 – 2.5
>25 – 30	3	2.0 – 2.4
>30 – 35	3.5	2.0 – 2.3

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.

9. Advice on correct administration

None.

10. Withdrawal periods

Not applicable.

11. Special storage precautions

Keep out of the sight and reach of children.

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

Do not use this veterinary medicinal product after the expiry date which is stated on the carton after Exp. The expiry date refers to the last day of that month.

Shelf life of half-tablets: 5 days.

12. Special precautions for disposal

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 applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

Pack sizes:
Cardboard box containing 1 blister of 10 tablets.
Cardboard box containing 10 blisters of 10 tablets.

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

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

16. Contact details

Marketing authorisation holder and contact details to report suspected adverse events:
KRKA, d.d, Novo mesto, Šmarješka cesta 6, 8501 Novo mesto, Slovenia

Manufacturer responsible for batch release:
KRKA, d.d, Novo mesto, Šmarješka cesta 6, 8501 Novo mesto, Slovenia
KRKA - FARMA d.o.o., V. Holjevca 20/E, 10450 Jastrebarsko, Croatia

Local representatives and contact details to report suspected adverse events:

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

17. Other information