PARTICULARS TO APPEAR ON THE OUTER PACKAGE

BOX

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Marfloquin 80 mg tablets for dogs
Marbofloxacin

2. STATEMENT OF ACTIVE SUBSTANCES

Each tablet contains:

Active substance:
Marbofloxacin…….80 mg

3. PHARMACEUTICAL FORM

Tablets.
The tablets can be divided into halves.

4. PACKAGE SIZE

12 tablets
72 tablets

5. TARGET SPECIES

Dogs

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.
Oral use.

8. WITHDRAWAL PERIOD(S)

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP:
Shelf life of half-tablets: 5 days.

11. SPECIAL STORAGE CONDITIONS

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

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only - to be supplied only on veterinary prescription.

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

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

KRKA, d.d., Novo mesto
Šmarješka cesta 6
8501 Novo mesto
Slovenia

16. MARKETING AUTHORISATION NUMBER(S)

Vm 01656/4049

17. MANUFACTURER'S BATCH NUMBER

Lot:

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

Blister

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Marfloquin 80 mg tablets for dogs
Marbofloxacin

2. NAME OF THE MARKETING AUTHORISATION HOLDER

KRKA

3. EXPIRY DATE

EXP:

4. BATCH NUMBER

Lot:

5. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

PACKAGE LEAFLET:
Marfloquin 80 mg tablets for dogs

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder:
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

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Marfloquin 80 mg tablets for dogs
Marbofloxacin

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

Each tablet contains 80 mg of marbofloxacin.

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.

4. INDICATION(S)

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 animals with known hypersensitivity to marbofloxacin or other (fluoro)quinolones or to 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.

6. ADVERSE REACTIONS

Mild side effects such as vomiting, softening of faeces, modification of thirst or transient increase in activity may very rarely 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:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

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 inform your veterinary surgeon.

7. TARGET SPECIES

Dogs.

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

For oral administration.

The recommended dose rate is 2 mg/kg/day (1 tablet for 40 kg 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 to avoid underdosing.

Duration of treatment:
- in 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.
- in 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.
- 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.

9. ADVICE ON CORRECT ADMINISTRATION

None.

10. WITHDRAWAL PERIOD(S)

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 after the expiry date 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 WARNING(S)

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.
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.
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.

Studies in laboratory animals (rat, rabbit) showed no embryotoxicity, teratogenicity and maternotoxicity with marbofloxacin at therapeutic doses.
The safety of marbofloxacin has not been assessed in pregnant and lactating cats and dogs.
Use only according to the benefit/risk assessment by the responsible veterinarian in pregnant and lactating animals.

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.

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

User warnings
People with known hypersensitivity to (fluoro)quinolones should avoid using this product.
In case of accidental ingestion seek medical attention and show product label and/or package leaflet to the doctor.
Wash hands after use.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.
Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

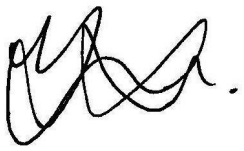
14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

October 2020

15. OTHER INFORMATION

Polyvinylchloride-aluminium-oriented polyamide/Aluminium cold formed blister containing 6 tablets.
Boxes with the instruction leaflet with 12 tablets and 72 tablets.
Not all pack sizes may be marketed.

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



Approved: 10 December 2020