Issued: May 2013
AN: 01888/2011

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ubiflox 80 mg tablets for dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

Active substance:
Marbofloxacin…….80 mg

Excipients:
For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Tablets.
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. CLINICAL PARTICULARS

4.1 Target species

Dogs.

4.2 Indications for use, specifying the 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.

4.3 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 animals with known hypersensitivity to marbofloxacin or other (fluoro)quinolones or to any of the excipients of the product.

4.4 Special warnings for each target species

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.

4.5 Special precautions for use

Special precautions for use in animals

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. In particular, no lesions of the articular joints were encountered in clinical studies at the recommended dose rate.

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 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.

4.6 Adverse reactions (frequency and seriousness)

Mild side effects such as vomiting, softening of faeces, modification of thirst or transient increase in activity may occasionally occur. These signs cease spontaneously after treatment and do not necessitate cessation of treatment.

4.7 Use during pregnancy, lactation or lay

Studies in laboratory animals (rat, rabbit) showed no embryotoxicity, teratogenicity and maternotoxicity with marbofloxacin at therapeutic doses. However no specific studies have been carried out in pregnant or lactating cats and dogs. Therefore, in these classes of animals, use only according to the benefit/risk assessment by the responsible veterinarian.

4.8 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.

4.9 Amounts to be administered and administration route

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.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

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

4.11 Withdrawal period(s)

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antibacterials for systemic use, Fluoroquinolones, ATCvet code: QJ01MA93

5.1 Pharmacodynamic properties

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 2009.

Microorganism	MIC (µg/ml)
Staphylococcus intermedius	0.23-0.25
Escherichia coli	0.125-0.25
Pasteurella multocida	0.04
Pseudomonas aeruginosa	0.94

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 mutation with three mechanisms: decrease of the bacterial wall permeability, expression of efflux pump or mutation of enzymes responsible for molecule binding.

5.2 Pharmacokinetic particulars

After oral administration in dogs 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 in dogs) predominantly in the active form in urine (2/3) and faeces (1/3).

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose monohydrate
Povidone (K 90)
Yeast powder
Meat flavour
Crospovidone
Castor oil, hydrogenated
Silica, Colloidal Anhydrous
Magnesium stearate

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale: 2 years
Shelf life of half-tablets: 5 days.

6.4. 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.

6.5 Nature and composition of immediate packaging

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

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

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

8. MARKETING AUTHORISATION NUMBER

Vm 01656/4052

9. DATE OF FIRST AUTHORISATION

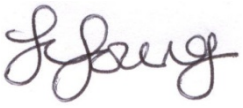
10 May 2013

10. DATE OF REVISION OF THE TEXT

May 2013

PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable.

Approved:  **10/05/2013**