marbocare® *flavour* 20mg

Tablets for dogs
Marbofloxacin

Statement of the active substances and other ingredients
Each tablet contains:
Active substance:
Marbofloxacin 20.0mg
Beige brown spotted round tablets with a cross-snap tab on one side. The tablet can be divided into halves or quarters.

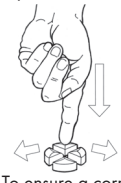
Indications
Marbofloxacin is indicated in the treatment of the following infections caused by susceptible strains of organisms (see Other Information section);
- Skin and soft tissue infections (skinfold pyoderma, impetigo, folliculitis, furunculosis, cellulitis).
- Urinary tract infections (UTI) associated or not with prostatitis or epididymitis
- Respiratory tract infections caused by susceptible strains of organisms.

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 5mg tablet is available.
Do not use in animals with known hypersensitivity to marbofloxacin or other (fluoro)quinolones or to any of the excipients.
Do not use in case of confirmed or suspected resistance to fluoroquinolones (cross resistance).

Adverse reactions
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.
If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

Target species
Dogs.

Dosage for each species, routes and method of administration
For oral administration.
The recommended dose rate is 2mg/kg/day in a single daily administration (see table below). The tablet can be divided into halves or quarters as follows;
- Place the tablet on a flat surface with the scored side facing up
- Break the tablet into four equal parts by pressing down with your thumb or finger onto the scored side.



Body Weight (kg)	Tablets
1.3 – 2.5	¼
2.6 – 5	½
5.1 – 7.5	¾
7.6 – 10	1
10.1 – 12.5	1¼
12.6 – 15	1½
15.1 – 20	2

To ensure a correct dosage body weight should be determined as accurately as possible to avoid underdosing.
- In skin and soft tissue infections, treatment duration is at least 5 days. 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. 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.

Special storage precautions
Keep out of the reach and sight of children.
This veterinary medicinal product does not require any special storage conditions.
Do not use after the expiry date stated on the blister and carton after "EXP"
Unused divided tablets should be returned to the blister pack and any divided tablet portions remaining after 96 hours (4 days) should be discarded.

Special warnings
Special precautions for use in animals
The 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. However at the therapeutic recommended dosage, no severe side-effects are to be expected in dogs.
Some fluoroquinolones at high doses may have an epileptogenic potential. Cautious use is recommended in dogs diagnosed as suffering from epilepsy.
A low urinary pH could have an inhibitory effect on the activity of marbofloxacin.
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.
Use during pregnancy, lactation or lay
Studies in laboratory animals (rats, rabbits) showed no teratogenicity, embryotoxicity and maternotoxicity with marbofloxacin at therapeutic doses.
The safety of marbofloxacin has not been assessed in pregnant and lactating dogs. Use only accordingly to the benefit/risk assessment by the responsible veterinarian in pregnant and lactating animals.
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.
When administered together with theophylline, the half-life and thus the plasma concentration of theophylline increases. Hence, in case of concurrent administration the dose of theophylline should be reduced.
Overdose (symptoms, emergency procedures, antidotes), if necessary
Overdosage may cause acute signs in the form of neurological disorders, which should be treated symptomatically.
User Warnings
People with known hypersensitivity to fluoroquinolones 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.

Special precautions for the disposal of unused product or waste material, 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.

Date on which the package leaflet was last approved: 26.06.13

Other information
For animal treatment only.
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.
Bacterial strains with a MIC ≤ 1µg/ml are susceptible, strains with a MIC of 2µg/ml are intermediately susceptible and strains with a MIC ≥ 4µg/ml are resistant to marbofloxacin (CLSI, 2004). MIC_{90} values of marbofloxacin for strains of *Staphylococcus (pseud)intermedius, Escherichia coli* and *Pasteurella multocida* isolated from diseased cats and dogs in Germany were 0.5µg/ml, 0.5µg/ml and 0.06µg/ml, respectively.
Resistance to fluoroquinolones occurs mostly by chromosomal mutation with three mechanisms: decrease of the bacterial wall permeability, expression of efflux pump or mutation of enzymes responsible for molecule binding.
Marbofloxacin is not active against anaerobes, yeasts or fungi.

Pack sizes
Box containing 1 blister of 10 tablets (10 tablets)
Box containing 2 blisters of 10 tablets (20 tablets)
Box containing 10 blisters of 10 tablets (100 tablets)
Not all pack sizes may be marketed.

Marketing Authorisation Holder: EMDOKA bvba, John Lijsenstraat 16, B-2321 Hoogstraten, Belgium

Manufacturer for the batch release: Lelypharma BV, Zuiveringsweg 42, 8243 PZ Lelystad, The Netherlands

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.
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Vm 34534/4004
POM-V
To be supplied only on veterinary prescription

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