

D3 Proposed Package Insert (1/2)

MARBOXA TAB 20

MacroPhar

Brand or Product Name : MARBOXA TAB 20

Name and Strength of Active Substance(s) :

Each tablet contains : Marbofloxacin 20 mg

Product Description : Pale yellow, round, biconvex tablet with breakline on one side and plane on the other side.

Pharmacodynamics

Marbofloxacin is a synthetic, bactericidal antimicrobial, belonging to the fluoroquinolone group which acts by inhibition of the 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. Marbofloxacin is not active against anaerobes, yeasts or fungi.

Pharmacokinetics

Absorption : After oral administration in dogs and cats 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.

Distribution, metabolism, excretion : 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 ($t_{1/2\beta}$ = 14 h) predominantly in the active form in urine (2/3) and faeces (1/3).

Indication :

In dogs : Marbofloxacin is indicated for the treatment of skin and soft tissue infections (skin fold pyoderma, impetigo, folliculitis, furunculosis, cellulitis), for the treatment of urinary tract infections associated or not with prostatitis and respiratory tract infections, caused by susceptible strains of organisms.

Recommended Dosage :

The recommended dose rate of Marbofloxacin is 2 mg/kg/day (1 tablet for 10 kg per day) in single daily administration.

In dogs :

- 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. Depending on the course of the disease it may be extended up to 21 days.

Mode of Administration :

Oral route

Contraindications :

- Marbofloxacin should not be used in dogs aged less than 12 months, or less than 18 months for exceptionally large breeds of dogs, such as Great Danes, Briard, Bernese Bonvier and Mastiffs, with a longer growth period.
- Do not use in cases of hypersensitivity to fluoroquinolones or 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.
- Not suitable for infections resulting from strict anaerobes, yeast or fungi.
- Do not use in cats.

Warnings and Precautions :

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.

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- The fluoroquinolones are also known for their potential neurological side effects. 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 package insert may increase the prevalence of bacteria resistant to the fluoroquinolones and may decrease the effectiveness of treatment with other quinolones due to the potential for cross resistance.

Precautions for the person administering the veterinary medical product to animals :

- 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 insert to the doctor. Wear gloves when handling or dividing tablets. Wash hands after use.

Interactions with Other Medicaments :

Fluoroquinolones are known to interact with orally administered cation (Aluminium, Calcium, Magnesium, Iron). In such cases, the bioavailability may be reduced.

Statement on usage during pregnancy and lactation :

Studies in pregnant rats and rabbits showed no side effects on pregnancy. However, no specified studies have been carried out in pregnant dogs.

Adverse Effects/ Undesirable Effects :

- 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. However, joint pain and/or neurological symptoms (ataxia, aggression, convulsion, depression) may occur on rare occasions.
- Allergic reactions have been observed (temporary skin reactions) due to histamine release that may occur.

- 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.

The frequency of adverse reactions is defined using the following convention :

- Rare (more than 1 but less than 10 animals in 10,000 animals treated)

Overdose and Treatment :

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

Withdrawal Period(s) :

Not applicable.

Storage Conditions :

Keep in tight containers. Protect from light. Store below 30°C.

Keep out of reach of children/ Jauhi daripada kanak-kanak

Dosage Forms and packaging available :

10 tablets are filled in a PVC-ALU blister and then 1, 2, 4, 5, 10, 50, 100 blisters are packed in carton.

Not all pack sizes may be marketed.

Date of Revision of Package Insert : 05/09/2024

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Name and Address of Manufacturer and Product Registration Holder :

Manufactured by : **MacroPhar Co., Ltd.**

89 Soi Pattanakarn 20 Yaek 4, Pattanakarn Road, Suan Luang, Bangkok 10250 Thailand.
Tel : (662)314-6671 Fax : (662)318-6091

Product Registration Holder : **Stadpharm Sdn. Bhd.**

E-9-01, Oasis Square, Ara Damansara, No. 2, Jalan PJU 1A/7A, 47301 Petaling Jaya, Selangor Darul Ehsan, Malaysia.

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