


Vétoquinol	Nom du produit : Marbocyl 80 mg MALAISIE	
Créé par : P. Mougenot	Référence article :	1213 D
le : 9/12/2014	Dimensions : 160x120 mm	
Visa :	1 couleur	rev D
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OVERDOSE AND TREATMENT

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

DOSAGE FORMS AND PACKAGING AVAILABLE

Tablet. 72 tablets (12 blisters of 6 tablets) and 12 tablets (2 blisters of 6 tablets)

**KEEP OUT OF REACH OF CHILDREN/
JAUHI DARIPADA KANAK-KANAK
STORE IN A DRY PLACE. DO NOT STORE ABOVE 25°C.**

Any unused product or waste materials should be disposed of in accordance with local requirements.

Date of revision: December 2014

Reg. number: MALXXXXXXHA

For animal treatment only

Registration holder:
GLADRON CHEMICALS SDN. BHD.
No. 7, Jalan TP 7,
UEP Industrial Park,
40400 Shah Alam,
Selangor Darul Ehsan,
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Manufactured by:
VETOQUINOL S.A.
Magny-Vernois
70200 Lure (France)

1213 D

Vétoquinol

Veterinary Pharmaceuticals
Magny-Vernois 70200 Lure (France)



Marbocyl P tablet 80mg

COMPOSITION

Marbofloxacin 80mg

PRODUCT DESCRIPTION

Beige brown spotted tablets

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

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. 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_{1/2β}= 14 h) predominantly in the active form in urine (2/3) and faeces (1/3).

INDICATIONS

Marbofloxacin is indicated in the treatment of:

- Skin and soft tissue infections (skin-fold pyoderma, impetigo, folliculitis, furunculosis, cellulitis) caused by susceptible strains of organisms.
- Urinary tract infections (UTI) associated or not with prostatitis caused by susceptible strains of organisms.

- Respiratory tract infections caused by susceptible strains of organisms.

DOSAGE AND ADMINISTRATION

Orally.

The recommended dose rate is 2 mg/kg/d (1 tablet for 40 kg per day) in single daily administration.

- 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.

CONTRA-INDICATIONS

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, Briards, Bernese Bouviers and Mastiffs, with a longer growth period.

Not suitable for infections resulting from strict anaerobes, yeast or fungi.

Do not use in cats. For the treatment of this species, a 5mg tablet is available.

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.

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.

WARNINGS AND PRECAUTIONS

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.

The fluoroquinolones are also known for their potential neurological side effects. Cautious use is recommended in dogs and cats 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 fluoroquinolones 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 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. Wear gloves when handling or dividing tablets. Wash hands after use.

INTERACTION WITH OTHER MEDICATIONS

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

PREGNANCY AND LACTATION

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