

PARTICULARS TO APPEAR ON THE OUTER PACKAGE CARTON

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Marbocyl P 20 mg tablet

2. STATEMENT OF ACTIVE SUBSTANCES

Each tablet contains:

Active substance:

Marbofloxacin 20mg

3. PACKAGE SIZE

Carton contains:

10 tablets

20 tablets

30 tablets

40 tablets

50 tablets

100 tablets

250 tablets

4. TARGET SPECIES

Dogs



5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Oral use.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}

9. SPECIAL STORAGE PRECAUTIONS

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Vetoquinol SA

14. MARKETING AUTHORISATION NUMBERS

Vm 06462/3014

15. BATCH NUMBER

Lot {number}

Vetoquinol logo

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING
UNITS- BLISTER**

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Marbocyl P 20 mg



2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Marbofloxacin 20mg

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

Vetoquinol logo

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Marbocyl P 20 mg tablet for dogs

2. Composition

Each tablet contains:

Active substance:

Marbofloxacin 20mg

Beige brown spotted round tablet.

3. Target species

Dogs



4. Indications for use

Infections caused by susceptible strains of organisms. The veterinary medicinal product is indicated in the treatment of:

Skin and soft tissue infections (skinfold pyoderma, impetigo, folliculitis, furunculosis, cellulitis).

Urinary tract infections (UTI) associated or not with prostatitis.

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 Bonvier and Mastiffs, with a longer growth period.

Do not use in cases of hypersensitivity to fluoroquinolones or any of the excipients.

Do not use in cases of resistance against quinolones since (almost) complete cross-resistance exists against other fluoroquinolones.

Do not use for infections resulting from strict anaerobes, yeast or fungi.
Do not use in cats. For the treatment of this species, a 5 mg tablet is available.

6. Special warnings

None.

Special precautions for safe use in the target species:

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.

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 the 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 the package leaflet or the label to the physician. Wear gloves when handling or dividing tablets. Wash hands after use.

Pregnancy:

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

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.

Overdose:

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

Major incompatibilities:

Not applicable.

7. Adverse events

Dogs:

Rare (1 to 10 animals / 10,000 animals treated):	Joint pain Neurological disorder (ataxia, seizure) Depression Aggression
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Allergic skin reaction ^{1,2} Vomiting ^{3,4} , loose stool ^{3,4} Excessive thirst ^{3,4} Hyperactivity ^{2,3,4}

At the therapeutic recommended dosage, no severe side-effects are to be expected in dogs and cats. In particular, no lesions of the articular joints were encountered in clinical studies at the recommended dose rate.

¹ Due to histamine release

² Transient

³ Mild

⁴ These signs cease spontaneously after treatment and do not necessitate cessation of treatment

Reporting adverse events is important. It allows continuous safety monitoring of a product. 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 contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system at:

Website: <https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine>

e-mail: adverse.events@vmd.gov.uk

8. Dosage for each species, routes and method of administration

Recommended dose rate:

To ensure a correct dosage, body weight should be determined as accurately as possible.

2 mg/kg/day in a single daily administration by oral route. The daily dose is achieved as follows:

Medium dogs : MARBOCYL®P 20 mg - 1 tablet per 10 kg bw

Duration of treatment:

- 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.

9. Advice on correct administration

10. Withdrawal periods

Not applicable.

11. Special storage precautions

Keep out of the sight and reach of children.

This veterinary medicinal product does not require any special storage conditions.

Do not use this veterinary medicinal product after the expiry date which is stated on label or carton after Exp. The expiry date refers to the last day of that month.

12. Special precautions for disposal

Medicines should not be disposed of via wastewater.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 06462/3014

Aluminium / aluminium blister strips containing 10 tablets/blister.

Cardboard box:

Pack sizes of 10, 20, 30, 40, 50, 100 and 250 tablets.

Not all pack sizes may be marketed.

15. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

16. Contact details

Marketing authorisation holder and manufacturer responsible for batch release and contact details to report suspected adverse reactions:

Vetoquinol SA
34 Rue de Chene Sainte-Anne
Magny-Vernois
70200 Lure
France
Tel: +44 (0)1280 814 500

17. Other information

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Gavin Hall
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