Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Marbocyl P 20 mg Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

Active substance:

Marbofloxacin 20 mg

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Tablet
Brown-beige spotted, circular divisible tablets.

4 CLINICAL PARTICULARS

4.1 Target Species

Dogs

4.2 Indications for use, specifying the target species

Marbofloxacin tablet is indicated in the treatment of:

Skin and soft tissue infections (intertrigo, folliculitis, impetigo, furunculosis, cellulitis) caused by susceptible strains.
Lower and upper urinary tract infections (UTI) associated or not with prostatitis or epididymitis caused by susceptible strains.
Respiratory tract infections caused by susceptible strains.

4.3 Contraindications

Do not use in animals with known hypersensitivity to the active ingredient. Do not use in dogs aged less than 12 months, or less than 18 months for giant breeds of dogs.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals

None.

Special precautions to be taken by the person administering the veterinary medicinal Product to Animals

None.

4.6 Adverse reactions (frequency and seriousness)

Hypersensitivity (allergic) reactions may occur in treated animals.

At the therapeutic recommended dosage, no severe side-effects are to be expected in dogs. 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. Mild side effects may occasionally occur such as vomiting, softening of faeces, modification of thirst or transient increase in activity. These signs cease spontaneously after treatment and do not necessitate cessation of treatment.

4.7 Use during pregnancy, lactation or lay

Marbofloxacin may be used in pregnant and lactating bitches.

4.8 Interaction with other medicinal products and other forms of interactions

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

4.9 Amounts to be administered and administration route

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

In skin and soft tissue infections, treatment duration is at least 5 days. Depending on clinical evolution, it may be extended up to 40 days. In lower urinary tract infections, treatment duration is at least 10 days. In case of associated prostatitis or epididymitis or in case of upper urinary tract infections, treatment 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

Overdose may cause acute signs in the form of neurological disorders which would have to be treated symptomatically.

4.11 Withdrawal period(s)

Not applicable.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antibacterials for systemic use, marbofloxacin.
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. 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.*

5.2 Pharmacokinetic particulars

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

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose Monohydrate
Povidone
Crospovidone
Liver Powder
Yeast powder
Silica, colloidal anhydrous
Hydrogenated Castor Oil
Magnesium Stearate

6.2 Major incompatibilities

Not applicable.

6.3 Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale: 3 years

6.4 Special precautions for storage

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

6.5 Nature and composition of immediate packaging

Marbofloxacin tablets are packaged in aluminium/aluminium thermoshaped blister packs.

Boxes of:
- 10 tablets (1 blister of 10 tablets)
- 20 tablets (2 blisters of 10 tablets)
- 30 tablets (3 blisters of 10 tablets)
- 40 tablets (4 blisters of 10 tablets)
- 50 tablets (5 blisters of 10 tablets)
- 100 tablets (10 blisters of 10 tablets)
- 160 tablets (16 blisters of 10 tablets)
- 170 tablets (17 blisters of 10 tablets)
- 180 tablets (18 blisters of 10 tablets)
- 190 tablets (19 blisters of 10 tablets
- 200 tablets (20 blisters of 10 tablets
- 250 tablets (25 blisters of 10 tablets)

Not all pack sizes may be marketed

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

Any unused product or waste material should be disposed of in accordance with national requirements.

7 MARKETING AUTHORISATION HOLDER

Vetoquinol Ireland Limited
12 Northbrook Road
Ranelagh
Dublin 6
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

VPA10983/054/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 19 April 2004
Date of last renewal: 18 April 2009

10 DATE OF REVISION OF THE TEXT

August 2019