SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Marbotab P 80 mg tablets for dogs

List of agreed names in the Member States where product is authorized.

Italy, Germany, France, The Netherlands, Belgium, Hungary	Marbotab P 80 mg tablets for dogs
Denmark	Marbotab P, 80 mg tablets, for dogs
United Kingdom, Ireland, Poland, Spain, Austria	Marbotab P, 80 mg tablets for dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

Active substance:
Marbofloxacin 80 mg

Excipients:
For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Tablet
Beige oblong tablet, white speckled, with breaking notch on both sides.
The tablets can be divided into halves.

4. CLINICAL PARTICULARS

4.1 Target species

Dogs

4.2 Indications for use, specifying the target species

Treatment of infections caused by strains of microorganisms susceptible to marbofloxacin.

- Skin and soft tissue infections (skinfold pyoderma, impetigo, folliculitis, furunculosis, cellulitis);
- Urinary tract infections (UTI) associated or not with prostatitis;
- Respiratory tract infections.

See section 5.1, Pharmcodynamic properties for further information on specific target pathogens.

4.3 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.

Not suitable for infections resulting from strict anaerobes, yeast or fungi.
Do not use in cases of hypersensitivity to fluoroquinolones or any of the excipients of the product.
Do not use in case of resistance against quinolones, since (almost) complete cross-resistance exists against and other fluoroquinolones.

Do not use Marbotab P 80 mg tablets in cats. For the treatment of this species, a divisible 20 mg tablet is available (Marbotab P 20 mg tablets).

4.4 Special warnings

None.

4.5 Special precautions for use

(i) 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 diagnosed as suffering from epilepsy.

A low urinary pH could have an inhibitory effect on the activity of marbofloxacin.

Official and local antimicrobial policies should be taken into account when the product is used.
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, fluoroquinolones should only be used based on susceptibility testing.
Use of the product deviating from the instructions given in the SmPC 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.

(ii) Special precautions to be taken by the person administering the veterinary medicinal product to animals

In case of accidental ingestion seek medical advice immediately and show the package leaflet or the label to the physician. Wear gloves when handling or dividing tablets. Wash hands after use.
People with known hypersensitivity to fluoroquinolones should avoid using this product.

4.6 Adverse reactions (frequency and seriousness)

At the therapeutic recommended dosage, no severe side-effects are to be expected. Mild side effects such as vomiting, allergic reactions, 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.
No lesions of the particular joints were encountered in clinical studies at the recommended dose rate. However, joint pain and/or neurological symptoms (ataxia, aggressiveness, convulsion, depression) may occur in rare occasions.

Allergic reactions have been observed (temporary skin reactions) due to the histamine release that may occur.

4.7 Use during pregnancy, lactation or lay

Safety in pregnant and lactating dogs and cats have not been established. Studies in pregnant rats and rabbits showed no side effects on pregnancy. Use in pregnant and lactating animals should be in accordance with the benefit/risk assessment performed by the responsible veterinarian.

4.8 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.

Do not use in combination with tetracyclines, macrolides because of the potential antagonist effect.

When administered together with theophylline, the half-life and thus the plasma concentration of theophylline increase. Hence, the dose of theophylline should be reduced.

4.9 Amounts to be administered and administration route

For oral administration. The recommended dose rate is 2 mg/kg/d in a single daily administration. To ensure a correct dosage body weight should be determined as accurately as possible to avoid underdosing.

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 not related to prostatitis or epididymitis, treatment duration is at least 10 days. In other cases, 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.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

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

4.11 Withdrawal period

Not applicable

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antibacterials for systemic use, Fluoroquinolone
ATC vet 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 (*Staphylococci (S. aureus and S. intermedius) and Streptococci*) and Gram negative bacteria (*Escherichia coli, Citrobacter freundii, Enterobacter cloacae, Proteus spp, Klebsiella pneuminiae, Pasteurella multicida, Pseudomonas aeruginosa, Bordetella bronchiseptica*) as well as *Mycoplasma spp*.

Cases of resistance have been observed in Streptococcus.
Strains with MIC ≤ 1 µg/ml are sensitive to marbofloxacin whereas strains with MIC ≥ 4 µg/ml are resistant to marbofloxacin.
Resistance to fluoroquinolones occurs 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.

5.2 Pharmacokinetic particulars

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 (elimination half-life is 14 hours in dogs and 10 hours in cats) predominantly in the active form in urine (2/3) and faeces (1/3).

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose monohydrate
Cellulose, powdered
Crospovidone
Colloidal anhydrous silica
Calcium behenate
Yeast, deactivated
Artificial beef flavour (PC-0125)

6.2 Incompatibilities

None known

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.
Shelf life of halved tablets: 24 hours.

6.4. Special precautions for storage

Store the blister in the original container.
If the tablets are divided, the remainig half should be kept in the blister pack. Any halved tablets remaining after 24 hours should be discarded.

6.5 Nature and composition of immediate packaging

Aluminium-Polyamide/Aluminium/PVC blister packs containing 10 tablets.
The blister packs are available in cartons of 20, 50, 100 and 200 tablets.

Not all pack sizes may be marketed.

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

CP-Pharma Handelsgesellschaft mbH
Ostlandring 13
31303 Burgdorf
Germany

8. MARKETING AUTHORISATION NUMBER

Vm 20916/4019

9. DATE OF FIRST AUTHORISATION

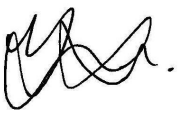
Date: 27 March 2013

10. DATE OF REVISION OF THE TEXT

Date: September 2014

PROHIBITION OR SUPPLY SALE AND OR USE

To be supplied only on veterinary prescription.



08 October 2014