

## **ANNEX I**

### **SUMMARY OF PRODUCT CHARACTERISTICS**

## **1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Marbotab P 80 mg tablets for dogs

## **2. QUALITATIVE AND QUANTITATIVE COMPOSITION**

Each tablet contains:

### **Active substance:**

Marbofloxacin 80 mg

For the full list of excipients, see section 6.1.

## **3. PHARMACEUTICAL FORM**

Tablet

Beige round tablet, white speckled, with breaking notch on one side.

The tablets can be divided into four quarters.

## **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, Pharmacodynamic 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 for each target species**

None.

#### **4.5 Special precautions for use**

##### 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.

##### 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 contact with veterinary medicinal 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 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.

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

- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

#### **4.7 Use during pregnancy, lactation or lay**

The safety of the veterinary medicinal product has not been established during pregnancy and lactation of dogs and cats. 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(s)**

Not applicable

## 5. PHARMACOLOGICAL PROPERTIES

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

Cases of resistance have been observed in *Streptococcus*.

Strains with MIC  $\leq 1$   $\mu\text{g/ml}$  are sensitive to marbofloxacin whereas strains with MIC  $\geq 4$   $\mu\text{g/ml}$  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  $\mu\text{g/ml}$  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 Major incompatibilities

None known.

### **6.3 Shelf life**

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

Shelf life of quartered tablets: 72 hours.

### **6.4. Special precautions for storage**

Store the blister in the original container.

If the tablets are divided, the remaining quarters should be kept in the blister pack. Any quartered tablets remaining after 72 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(S)**

To be completed nationally.

## **9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

Date of first authorisation: to be completed nationally

Date of last renewal: to be completed nationally

## **10. DATE OF REVISION OF THE TEXT**

{MM/YYYY}

## **PROHIBITION OF SALE, SUPPLY AND/OR USE**

To be supplied only on veterinary prescription.

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

Germany, Hungary	Marbotab P 80 mg tablets for dogs
Spain	Marbotab 80 mg tablets for dogs

### **ANNEX III**

### **LABELLING AND PACKAGE LEAFLET**



## **A. LABELLING**

## **PARTICULARS TO APPEAR ON THE OUTER PACKAGE**

### **CARTON BOX**

#### **1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Marbotab <P> 80 mg tablets for dogs  
Marbofloxacin

#### **2. STATEMENT OF ACTIVE SUBSTANCES**

Each tablet contains:  
Marbofloxacin 80 mg

#### **3. PHARMACEUTICAL FORM**

Tablet

#### **4. PACKAGE SIZE**

20 tablets  
50 tablets  
100 tablets  
200 tablets

#### **5. TARGET SPECIES**

Dogs

#### **6. INDICATION(S)**

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 infection

Read the package leaflet before use.

#### **7. METHOD AND ROUTE(S) OF ADMINISTRATION**

For oral use.

#### **8. WITHDRAWAL PERIOD (S)**

#### **9. SPECIAL WARNING(S), IF NECESSARY**

Wear gloves when handling or dividing tablets. Wash hands after use.

**10. EXPIRY DATE**

EXP <month/year>

Shelf life of divided tablets: 72 hours.

**11. SPECIAL STORAGE CONDITIONS**

Store the blisters in the original container.

If the tablets are divided, the remaining quarters should be kept in the blister pack.

**12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY**

Read the package leaflet before use.

**13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE**

For animal treatment only. To be supplied only on veterinary prescription.

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

Keep out of the sight and reach of children.

**15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER**

CP-Pharma Handelsges. mbH  
Ostlandring 13  
31303 Burgdorf  
Germany

**16. MARKETING AUTHORISATION NUMBER(S)**

<to be completed nationally>

**17. MANUFACTURER’S BATCH NUMBER**

Batch <number>

<b>MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS</b>
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<b>BLISTER</b>
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<b>1. NAME OF THE VETERINARY MEDICINAL PRODUCT</b>
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Marbotab P 80 mg tablets for dogs  
Marbofloxacin

<b>2. NAME OF THE MARKETING AUTHORISATION HOLDER</b>
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CP-Pharma Handelsges. mbH

<b>3. EXPIRY DATE</b>
-----------------------

EXP <month/year>

<b>4. BATCH NUMBER</b>
------------------------

Batch <number>

<b>5. THE WORDS “FOR ANIMAL TREATMENT ONLY”</b>
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For animal treatment only.

## **B. PACKAGE LEAFLET**

## **PACKAGE LEAFLET**

Marbotab P 80 mg tablets for dogs

### **1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT**

Marketing authorisation holder and manufacturer responsible for batch release:

CP-Pharma HandelsGES. mbH

Ostlandring 13

31303 Burgdorf

Germany

### **2. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Marbotab P 80 mg tablets for dogs

Marbofloxacin

### **3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENTS**

Per tablet:

#### **Active substance:**

Marbofloxacin: 80 mg

Beige round tablet, white speckled, with breaking notch on one side.

The tablets can be divided into four quarters.

### **4. INDICATION(S)**

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.

### **5. 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 case of resistance against quinolones, since (almost) complete cross-resistance exists against and other fluoroquinolones.

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

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).

## **6. ADVERSE REACTIONS**

At the therapeutic recommended dosage, no severe side-effects are to be expected. Mild side effects such as vomiting, softening of faeces, modification of thirst or transient increase in activity may 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.

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

- very common (more than 1 in 10 animals treated displaying adverse reaction(s) )
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated )
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

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 inform your veterinary surgeon.

## **7. TARGET SPECIES**

Dogs

## **8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION**

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. Tablets may be divided along score lines to facilitate accurate dosing.

### 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 prostates or epididymis, 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.

## **9. ADVICE ON CORRECT ADMINISTRATION**

## **10. WITHDRAWAL PERIOD(S)**

Not applicable

## **11. SPECIAL STORAGE PRECAUTIONS**

Keep out of the sight and reach of children.

Store in the original package (blister). If the tablets are quartered, the remaining quarters should be kept in the blister pack. Any quartered tablets remaining after 72 hours should be discarded.

Do not use this veterinary medicinal product after the expiry date which is stated on the carton and blister after EXP.

## **12. SPECIAL WARNING(S)**

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. Caution 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.

Special precautions to be taken by the person administering the product to the 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.

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.

Use in pregnant and lactating animals should be in accordance with the benefit/risk assessment performed by the responsible veterinarian.

Interactions with other medicinal products or 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.



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.

Overdose (symptoms, emergency procedures, antidotes):

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

**13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY**

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

**14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED**

To be completed nationally

**15. OTHER INFORMATION**

The blister packs are available in cartons of 20, 50, 100 and 200 tablets.  
Not all pack sizes may be marketed.