Marbotab P 80 mg tablets for dogs

PART **1 B 2**
Proposal for Packaging, 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 AND OTHER SUBSTANCES

Each tablet contains:
Marbofloxacin 80 mg

3. PHARMACEUTICAL FORM

Tablet

4. PACKAGE SIZE

20, 50, 100 and 200 tablets

5. TARGET SPECIES

Dogs

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For oral use. Read the package leaflet before use.

8. WITHDRAWAL PERIOD

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP: <month/year>
Shelf life of halved tablets: 24 hours.

11. SPECIAL STORAGE CONDITIONS

Store the blisters in the original container.
If the tablets are divided, the remaining half tablet 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.
<IE: POM>

14. THE WORDS "KEEP OUT OF THE REACH AND SIGHT OF CHILDREN"

Keep out of the reach and sight 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>
<UK: 20916/4019>
<IE: 10810/011/002>

17. MANUFACTURER'S BATCH NUMBER

Batch: <number>

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

BLISTER

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Marbotab P 80 mg tablets for dogs
Marbofloxacin

2. NAME OF THE MARKETING AUTHORISATION HOLDER

CP-Pharma Handelsges. mbH

3. EXPIRY DATE

EXP: <month/year>

4. BATCH NUMBER

Batch: <number>

5. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

<National issue:>
<IE: POM>

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

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

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 expectedMild 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.
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.

If you notice any serious effects or other effects not mentioned in this leaflet, 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 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.

9. ADVICE ON CORRECT ADMINISTRATION

10. WITHDRAWAL PERIOD

Not applicable

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the reach and sight of children.
Store in the original package (blister). If the tablets are halved, the remaining half tablet should be kept in the blister pack. Any halved tablets remaining after 24 hours should be discarded.
Do not use after the expiry date stated on the carton and blister after EXP.

12. SPECIAL WARNING(S)

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.

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.

Use during 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
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
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

MA number:
<to be established nationally>
<UK: 20916/4019>
<IE: 10810/011/002>

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

National issue:
<IE: POM – Prescription Only Medicine>