SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

MARBOCYL Vet 80 mg tablets for dogs (in Denmark and in Sweden)
MARBOCYL P 80 mg tablets, for dogs (in Austria and in Greece)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance:
Marbofloxacin 80 mg

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Tablets
Beige brown-spotted oblong tablets, divisible in halves.

4. CLINICAL PARTICULARS

4.1 Target species

Dogs

4.2 Indications for use, specifying the target species

Treatment of skin and soft tissue infections, in dogs, caused by susceptible strains of organisms.
Treatment of urinary tract infections in dogs, caused by susceptible strains of organisms.

4.3 Contraindications

Do not administer in growing dogs less than 8 to 18 months of age, depending on the size of the breed.
Do not use in combination with non-steroidal anti-inflammatory drugs (NSAIDs) in dogs with a history of seizures.

4.4 Special warnings

No available information about potential retinal damage.

4.5 Special precautions for use

Special precautions for use in animals
Do not use in dogs with known quinolone hypersensitivity.
Do not administer to male dogs used for breeding, as no data on the fertility in male dogs are available.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
Do not handle the product if you have known hypersensitivity to fluoroquinolones.
Medicinal advice should be sought in the event of accidental ingestion, particularly by a child.

Other precautions
Heavy reliance on a single class of antibiotic may result in the induction of resistance in a bacterial population. It is prudent to reserve the fluoroquinolones for the treatment of clinical conditions, which have responded poorly, or are expected to respond poorly, to other classes of antibiotics. Marbocyl Vet should only be used based on susceptibility testing.

4.6 Adverse reactions (frequency and seriousness)

Mild side effects such as vomiting, allergic reaction, articular pain, softening of faeces, modification of thirst or transient increase in activity may occasionally occur. These signs cease spontaneously after treatment.

4.7 Use during pregnancy, lactation or lay

Do not administer in pregnant and lactating animals.

4.8 Interaction with other medicinal products and other forms of interaction

In case of concomitant oral administration with cations (aluminium, calcium, magnesium, iron), the bioavailability of marbofloxacin may be reduced.
The dosage of theophylline must be reduced when used concurrently.
Fluoroquinolones should not be used in combination with non-steroidal anti-inflammatory drugs (NSAIDs) in dogs with a history of seizures.

4.9 Amounts to be administered and administration route

The recommended dose rate is 2 mg/kg once daily, in dogs. The tablets have to be administered directly in mouth or mixed in food.

The posology may be calculated as follows:
Large size dogs: 80 mg (1 tablet) per 40 kg

Duration of treatment:
Dogs:
- 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.

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

Only very high dose (> 2000 mg/kg) may cause acute signs in the form of neurological disorders, which should be treated symptomatically.

4.11 Withdrawal period(s)

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

ATCvet code: QJ01MA93 (fluoroquinolone)

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) and Gram negative bacteria (*Escherichia coli, Salmonella spp, Citrobacter freundii, Enterobacter cloacae, Morganella morganii, Proteus spp, Klebsiella spp, Shigella spp, Pasteurella spp, Haemophilus spp, Moraxella spp, Pseudomonas spp, Brucella canis)* as well as *Mycoplasma spp.*
Acquired resistance to fluoroquinolones is related to chromosome mutations. A long term survey of the antimicrobial susceptibility of key pathogens isolated in Europe did not show an increase of the acquired resistance over the past years.

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 1.4 µg/ml within 2.5 hours in dogs and 1.5 µg/ml within 1.5 hours in cats. Its bioavailability is high.

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 in dogs and 10 h 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,
Povidone,
Crospovidone
Porcine liver powder
Yeast powder
Anhydrous colloidal silica,
Hydrogenated castor oil,
Magnesium stearate

6.2 Incompatibilities

None known.

6.3 Shelf life

3 years.

6.4. Special precautions for storage

None.

6.5 Nature and composition of immediate packaging

Marbocyl Vet tablets are packaged in aluminium/aluminium thermoshaped blisters, packed in cardboard boxes.
Each blister contains 6 beige brown-spotted oblong tablets of Marbocyl Vet., 80 mg

Box containing 6, 12, 18, 24, 30, 48, 72, 96, 120, 240, or 480 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 product or waste materials should be disposed of in accordance with national requirements.

7. MARKETING AUTHORISATION HOLDER

To be adapted according to countries

8. MARKETING AUTHORISATION NUMBER(S)

To be adapted according to countries

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

<{DD/MM/YYYY}> <{DD month YYYY}>…

10 DATE OF REVISION OF THE TEXT

{MM/YYYY} or <month YYYY>

PROHIBITION OF SALE, SUPPLY AND/OR USE

LABELLING AND PACKAGE LEAFLET

A. LABELLING

<PARTICULARS TO APPEAR ON THE OUTER PACKAGE>
<PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE>

{NATURE/TYPE}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

MARBOCYL Vet 80 mg tablets for dogs (in Denmark and in Sweden)
MARBOCYL P 80 mg tablets, for dogs (in Austria and in Greece)
Marbofloxacin

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Marbofloxacin 80 mg

3. PHARMACEUTICAL FORM

Tablets divisible in halves

4. PACKAGE SIZE

6 tablets
12 tablets
18 tablets
24 tablets
30 tablets
48 tablets
72 tablets
96 tablets
120 tablets
240 tablets
480 tablets

5. TARGET SPECIES

Dogs

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Not applicable.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}

11. SPECIAL STORAGE CONDITIONS

None.

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

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

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 REACH AND SIGHT OF CHILDREN"

Keep out of the reach and sight of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

[To be completed nationally.]

16. MARKETING AUTHORISATION NUMBER(S)

[To be completed nationally.]

17. MANUFACTURER'S BATCH NUMBER

Lot

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

{NATURE/TYPE}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

MARBOCYL Vet 80 mg tablets for dogs (in Denmark and in Sweden)
MARBOCYL P 80 mg tablets, for dogs (in Austria and in Greece)
Marbofloxacin

2. NAME OF THE MARKETING AUTHORISATION HOLDER

Vetoquinol

3. EXPIRY DATE

EXP {month/year}

4. BATCH NUMBER

Lot

5. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET

MARBOCYL Vet 80 mg tablets for dogs (in Denmark and in Sweden)
MARBOCYL P 80 mg tablets, for dogs (in Austria and in Greece)

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>>:
To be completed nationally

<Manufacturer for the batch release:>
To be completed nationally

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

MARBOCYL Vet 80 mg tablets for dogs (in Denmark and in Sweden)
MARBOCYL P 80 mg tablets, for dogs (in Austria and in Greece)
Marbofloxacin

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

Marbofloxacin .....80 mg

Beige brown-spotted oblong tablets divisible in halves

4. INDICATIONS

Treatment of skin and soft tissue infections, in dogs, caused by susceptible strains of organisms.
Treatment of urinary tract infections, in dogs, caused by susceptible strains in organisms.

5. CONTRAINDICATIONS

Do not administer in growing dogs less than 8 to 18 months of age, depending on the size of the breed.
Do not use in combination with non-steroidal anti-inflammatory drugs (NSAIDs) in dogs with a history of seizures.

6. ADVERSE REACTIONS

Mild side effects such as vomiting, allergic reaction, pain in the joints, softening of faeces, modification of thirst or transient increase in activity may occasionally occur, but these signs cease spontaneously after treatment.

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

The recommended dose rate is 2 mg/kg once daily, in dogs. The tablets have to be given directly in the mouth or mixed in food.

The posology may be calculated as follows:
Large size dogs: 80 mg (1 tablet) per 40 kg

How long the treatment should continue:
Dogs:
- In skin and soft tissue infections, treatment should continue for at least 5 days. Depending on the course of the disease, it may be extended up to 40 days.
- In urinary tract infections, treatment should continue for at least 10 days. Depending on the course of the disease, it may be extended up to 28 days.

9. ADVICE ON CORRECT ADMINISTRATION

None.

10. WITHDRAWAL PERIOD

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the reach and sight of children.
This veterinary medicinal product does not require any special storage conditions.
Do not use after the expiry date stated on the label and carton after EXP.

12. SPECIAL WARNING(S)

No available information about potential retinal damage.

Special precautions for use in animals
Do not use in dogs with known quinolone hypersensitivity.
Do not administer to male dogs used for breeding, as no data on the fertility in male dogs are available.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
Do not handle the product if you have known hypersensitivity to fluoroquinolones.
Medicinal advice should be sought in the event of accidental ingestion, particularly by a child.

Other precautions
Heavy reliance on a single class of antibiotic may result in the induction of resistance in a bacterial population. It is prudent to reserve the fluoroquinolones for the treatment of clinical conditions, which have responded poorly, or are expected to respond poorly, to other classes of antibiotics. Marbocyl should only be used based on susceptibility testing.

Use during pregnancy, lactation or lay

Do not administer in pregnant and lactating animals.

Interaction with other medicinal products and other forms of interaction

In case of concomitant oral administration with cations (aluminium, calcium, magnesium, iron), the effect of marbofloxacin may be reduced.
The dosage of theophylline must be reduced when used concurrently.
Fluoroquinolones should not be used in combination with non-steroidal anti-inflammatory drugs (NSAIDs) in dogs with a history of seizures.

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

Only very high dose (> 2000 mg/kg) may cause acute signs in the form of neurological disorders, which should be treated symptomatically.

Incompatibilities
None known.

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

Medicines should not be disposed of via wastewater or household waste.
Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

Box containing 6, 12, 18, 24, 30, 48, 72, 96, 120, 240, or 480 tablets

Not all pack sizes may be marketed