Summary of Product Characteristics

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Enrotab 50 mg tablets for dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

Active substance
Enrofloxacin 50.0 mg

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

3. PHARMACEUTICAL FORM

Tablet
A white to slightly yellow, round, convex snap-tab tablet
The tablet can be divided into equal halves.

4. CLINICAL PARTICULARS

4.1 Target species

Dogs

4.2 Indications for use, specifying the target species

In dogs:
- treatment of lower urinary tract infections (associated or not with prostatitis) and upper urinary tract infections caused by *Escherichia coli* or *Proteus mirabilis*.
- Treatment of superficial and deep pyoderma.

4.3 Contraindications

Do not use in young or growing dogs (dogs aged less than 12 months (small breed) or less than 18 months (large breed)) as the product may cause epiphyseal cartilage alterations in growing puppies.

Do not use in dogs having seizure disorders, since enrofloxacin may cause CNS stimulation.
Do not use in dogs with known hypersensitivity to fluoroquinolones or to any of the excipients of the product.
Do not use in case of resistance to quinolones, as there exists almost complete cross resistance to other quinolones and complete cross resistance to other fluoroquinolones.

Do not use with tetracyclines, phenicols or macrolides because of potential antagonistic effects.
Pregnant and lactating animals, please see section 4.7.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals

It is prudent to reserve the fluoroquinolones for the treatment of clinical conditions that have responded poorly, or are expected to respond poorly, to other classes of antibiotics. Whenever possible, fluoroquinolones should only be used based on susceptibility testing. Official and local antimicrobial policies should be taken into account when the product is used. Use of the product deviating from the instructions given in the SPC may increase the prevalence of bacteria resistant to fluoroquinolones and may decrease the effectiveness of treatment with other quinolones due to the potential cross resistance.

Use the product with caution in dogs with severe renal or hepatic impairment.
Pyoderma is mostly secondary to an underlying disease. It is advisable to determine the underlying cause and to treat the animal accordingly.

Use of the product deviating from instructions given in the SPC may increase the prevalence of bacteria resistant to 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 to the physician.
Wash hands after handling the product.
In case of contact with the eyes, rinse immediately with plenty of water.
Do not handle the product in case of known hypersensitivity to the product

4.6 Adverse reactions (frequency and seriousness)

- Hypersensitivity reactions
- Alterations in Central Nervous System

Possible joint cartilage alterations in growing puppies (see 4.3 contraindications).
In rare cases vomiting and anorexia are observed.

4.7 Use during pregnancy, lactation or lay

Use during pregnancy:

Studies in laboratory animals (rat, chinchilla) have not produced any evidence of a teratogenic, foetotoxic, maternotoxic effect. Use only according to the benefit/risk assessment by the responsible veterinarian.

Use during lactation:
As enrofloxacin passes into the maternal milk, the use is not recommended during lactation.

4.8 Interaction with other medicinal products and other forms of interaction

Concurrent use of flunixin should be under careful veterinary monitoring, as the interactions between these drugs may lead to adverse events related to delayed elimination.
Concomitant administration of theophylline requires careful monitoring as serum levels of theophylline may increase.
Concurrent use of magnesium or aluminium containing substances (such as antacids or sucralfate) may reduce absorption of enrofloxacin. These drugs should be administered two hours apart.
Do not administer simultaneously with tetracyclines, phenicols or macrolides because of potential antagonistic affects.
Do not administer simultaneously with non-steroidal antiinflamatory drugs, convulsions can occur

4.9 Amounts to be administered and administration route

Oral use

5 mg of enrofloxacin/kg/day as a single daily dosing, i.e. one tablet for 10 kg daily for:
- 10 days in lower urinary tract infections
- 15 days in upper urinary tract infections and lower urinary tract infections associated with prostatitis
- Up to 21 days in superficial pyoderma depending on clinical response
- Up to 49 days in deep pyoderma depending on clinical response

The treatment should be considered in case of lack of clinical improvement at half of the treatment duration.
The tablets may be administered directly in the mouth of the dog or simultaneously with food if necessary.
Do not exceed the recommended treatment dose.
After breaking a tablet, use the remaining tablet halve for the next dose. Store the tablet halve in the original blister pocket

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

Overdosing can cause vomiting and nervous signs (muscle tremor, incoordination and convulsions) which may require treatment discontinuation.
In the absence of any known antidote, apply drug elimination methods and symptomatic treatment.
If necessary, administration of aluminium- or magnesium-containing antacids or activated carbon can be used to reduce absorption of enrofloxacin.
According to literature, signs of overdosage with enrofloxacin in dogs such as inappetence and gastrointestinal disturbance were observed at approximately 10 times the recommended

dose when administered for two weeks. No signs of intolerance were observed in dogs administered 5 times the recommended dose for a months.

4.11 Withdrawal period(s)

Not applicable

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Fluoroquinolone antibiotics
ATCvet code: QJ01MA90

5.1 Pharmacodynamic properties

Enrofloxacin is a synthetic fluoroquinolone antibiotic that exerts its activity by inhibiting topoisomerase II, an enzyme involved in the mechanism of bacterial replication.

Enrofloxacin exerts bactericidal activity concentration-dependant with similar values of minimal inhibit concentration and minimal bactericide concentrations. It also possesses activity against bacteria in the stationary phase by an alteration of the permeability of the outer membrane phospholipid cell wall.

In general, enrofloxacin exhibits good activity against most gram-negative bacteria, especially those of the ENterobacteriacea. *Escherichia coli*, *Klebsiella spp.*, *Proteus spp.*, and *Enterobacter spp.* Are generally susceptible.
Pseudomonas aeruginosa is variably susceptible and, when it is susceptible, usually has a higher MIC than other susceptible organisms.
Staphylococcus aureus and *Staphylococcus intermedius* usually are susceptible.
Streptococci, enterococci, anaerobic bacteria can generally be considered resistant.

Induction of resistance against quinolones can develop by mutations in the gyrase gene of bacteria and by changes in cell permeability towards quinolones.

5.2 Pharmacokinetic particulars

Enrofloxacin is approximately 100% bioavailable after oral administration. It is unaffected by food. Enrofloxacin is rapidly metabolized to form an active compound, ciprofloxacin.
After a dose of 5 mg/kg body weight, maximum plasma levels of approximately 1.5 µg/mL in dogs are reached after 0.5 to 2.0 hours.

Enrofloxacin is primarily excreted via the kidneys. A major portion of the parent drug and its metabolites is recovered in urine.
Enrofloxacin is widely distributed in the body. The tissue concentrations are often higher than the serum concentrations. Enrofloxacin crosses the blood-brain barrier. The degree of protein binding in serum is 14% in dogs. The half-life is approximately 3.0 hours for dogs.
Approximately 25% of the dose of enrofloxacin is excreted in the urine and 75% via the faeces. Approximately 60% of the dose is excreted as unchanged enrofloxacin in the urine and the remainder as metabolites, amongst others ciprofloxacin. The total clearance is approximately 9 mL/minute/kg bodyweight.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose monohydrate
Maize starch
Povidone K25
Cellulose, powdered
Croscarmellose sodium
Crospovidone
Colloidal anhydrous silica
Magnesium stearate

6.2 Incompatibilities

Not applicable

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years
Shelf-life after first opening the immediate packaging: 24 hours

6.4. Special precautions for storage

Veterinary medicinal product as packaged for sale: No special precautions for storage.
Divided tablets: Store below 25°C.
Divided tablets should be stored in the blister pack.
Any divided tablet portions remaining after 24 hours should be discarded.

6.5 Nature and composition of immediate packaging

Alu-PVC/PE/PVDC blister or Alu-PVC/PVDC blister with 10 tablets;
Box with 1 blister (10 tablets);
Box with 2 blisters (20 tablets);
Box with 3 blisters (30 tablets);
Box with 5 blisters (50 tablets);
Box with 6 blisters (60 tablets);
Box with 10 blisters (100 tablets);
Box with 15 blisters (150 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 product should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

CP-Pharma Handelsges. mbH
Ostlandring 13
31303 Burgdorf
Germany

8. MARKETING AUTHORISATION NUMBER(S)

9. DATE OF FIRST AUTHORISATION

10. DATE OF REVISION OF THE TEXT

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Carton

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Enrotab 50 mg tablets for dogs
Enrofloxacin

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each tablet contains:
Enrofloxacin 50.0 mg

3. PHARMACEUTICAL FORM

Tablets

4. PACKAGE SIZE

10/ 20/30/50/60/100/150 tablets

5. TARGET SPECIES

Dogs

6. INDICATIONS

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

10. EXPIRY DATE

EXP: (month/year)

11. SPECIAL STORAGE CONDITIONS

Veterinary medicinal product as packaged for sale: No special precautions for storage.
Divided tablets: Store below 25^0C.
Divided tablets should be stored in the blister pack.
Any divided tablet portions remaining after 24 hours should be discarded.

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

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

{xxxxx}

17. MANUFACTURER'S BATCH NUMBER

Lot:

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

BLISTERS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Enrotab 50 mg tablets for dogs
enrofloxacin

2. NAME OF THE MARKETING AUTHORISATION HOLDER

CP-Pharma Handelsges. mbH

3. EXPIRY DATE

EXP {month/year}

4. BATCH NUMBER

Lot {number}

5. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only – to be supplied only on veterinary prescription.

PACKAGE LEAFLET

Enrotab 50 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:

CP-Pharma Handelsges. mbH
Ostlandring 13
31303 Burgdorf
Germany

Manufacturer responsible for batch release:

Artesan Pharma GmbH & Co KG
Wendlandstrasse 1
29439 Lüchow
Germany

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Enrotab 50 mg tablets for dogs

Enrofloxacin

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

Enrotab 50 mg is a slightly yellow, round, convex snap-tab tablet for oral administration to dogs.
The tablet can be divided into equal halves.

Each tablet contains:

Active substance: Enrofloxacin 50.0 mg

4. INDICATION(S)

In dogs:

- treatment of lower urinary tract infections (associated or not with prostatitis) and upper urinary tract infections caused by *Escherichia coli* or *Proteus mirabilis*.

Treatment of superficial and deep pyoderma.

5. CONTRAINDICATIONS

Do not use in young or growing dogs (dogs aged less than 12 months (small breed) or less than 18 months (large breed)) as the product may cause epiphyseal cartilage alterations in growing puppies.
Do not use in dogs having seizure disorders, since enrofloxacin may cause CNS stimulation.
Do not use in dogs with known hypersensitivity to fluoroquinolones or to any of the excipients of the product.
Do not use in case of resistance to quinolones, as there exists almost complete cross resistance to other quinolones and complete cross resistance to other fluoroquinolones.
Do not use with tetracyclines, phenicols or macrolides because of potential antagonistic effects.

6. ADVERSE REACTIONS

- Hypersensitivity reactions
- Alterations in Central Nervous System

Possible joint cartilage alterations in growing puppies (see 4.3 contraindications).
In rare cases vomiting and anorexia are observed.

If you notice any serious effects or other effects not mentioned in this package leaflet, please inform your veterinary surgeon

7. TARGET SPECIES

Dogs

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

Oral use

5 mg of enrofloxacin/kg/day as a single daily dosing, i.e. one tablet for 10 kg daily for:

- 10 days in lower urinary tract infections
- 15 days in upper urinary tract infections and lower urinary tract infections associated with prostatitis
- Up to 21 days in superficial pyoderma depending on clinical response
- Up to 49 days in deep pyoderma depending on clinical response

The treatment should be considered in case of lack of clinical improvement at half of the treatment duration.
The tablets may be administered directly in the mouth of the dog or simultaneously with food if necessary.

Do not exceed the recommended treatment dose.

9. ADVICE ON CORRECT ADMINISTRATION

After breaking a tablet, use the remaining tablet halve for the next dose. Store the tablet halve in the original blister pocket

10. WITHDRAWAL PERIOD

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Do not use this veterinary medicinal product after the expiry date which is stated on the blister and carton after "EXP". The expiry date refers to the last day of that month.
Veterinary medicinal product as packaged for sale: No special precautions for storage.
Divided tablets: Store below 25°C.
Divided tablets should be stored in the blister pack.
Any divided tablet portions remaining after 24 hours should be discarded.

12. SPECIAL WARNING(S)

Special precautions for use in animals
It is prudent to reserve the fluoroquinolones for the treatment of clinical conditions that have responded poorly, or are expected to respond poorly, to other classes of antibiotics. Whenever possible, fluoroquinolones should only be used based on susceptibility testing. Official and local antimicrobial policies should be taken into account when the product is used. Use of the product deviating from the instructions given in the SPC may increase the prevalence of bacteria resistant to fluoroquinolones and may decrease the effectiveness of treatment with other quinolones due to the potential cross resistance.
Use the product with caution in dogs with severe renal or hepatic impairment.
Pyoderma is mostly secondary to an underlying disease. It is advisable to determine the underlying cause and to treat the animal accordingly.

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 to the physician.
Wash hands after handling the product.
In case of contact with the eyes, rinse immediately with plenty of water.
Do not handle the product in case of known hypersensitivity to the product

Use during pregnancy, lactation or lay
Use during pregnancy:
Studies in laboratory animals (rat, chinchilla) have not produced any evidence of a teratogenic, foetotoxic, maternotoxic effect. Use only according to the benefit/risk assessment by the responsible veterinarian.

Use during lactation:
As enrofloxacin passes into the maternal milk, the use is not recommended during lactation.

Interaction with other medicinal products and other forms of interaction
Concurrent use of flunixin should be under careful veterinary monitoring, as the interactions between these drugs may lead to adverse events related to delayed elimination.
Concomitant administration of theophylline requires careful monitoring as serum levels of theophylline may increase.
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Do not administer simultaneously with tetracyclines, phenicols or macrolides because of potential antagonistic affects.
Do not administer simultaneously with non-steroidal antiinflamatory drugs, convulsions can occur

Overdose (symptoms, emergency procedures, antidotes), if necessary
Overdosing can cause vomiting and nervous signs (muscle tremor, incoordination and convlusions) which may require treatment discontinuation.
In the absence of any known antidote, apply drug elimination methods and symptomatic treatment.
If necessary, administration of aluminium- or magnesium-containing antacids or activated carbon can be used to reduce absorption of enrofloxacin.
According to literature, signs of overdosage with enrofloxacin in dogs such as inappetence and gastrointestinal disturbance were observed at approximately 10 times the recommended dose when administered for two weeks. No signs of intolerance were observed in dogs administered 5 times the recommended dose for a months.

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

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

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

<MM/JJJJ>

15. OTHER INFORMATION

Alu-PVC/PE/PVDC blister or Alu-PVC/PVDC blister with 10 tablets;
Box with 1 blister (10 tablets);
Box with 2 blisters (20 tablets);
Box with 3 blisters (30 tablets);
Box with 5 blisters (50 tablets);
Box with 6 blisters (60 tablets);
Box with 10 blisters (100 tablets);
Box with 15 blisters (150 tablets);

Not all pack sizes may be marketed.