SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Zobuxa 150 mg tablets for dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

One tablet contains :

Active substance:
Enrofloxacin 150 mg

Excipients:

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Tablet
Beige-coloured, round, slightly dotted tablet with score line on both sides. The tablets can be divided into two equal parts.

4. CLINICAL PARTICULARS

4.1 Target species

Dogs

4.2 Indications for use, specifying the target species

Treatment of bacterial infections of the alimentary, respiratory and urogenital tracts, skin, wound infections and otitis externa.

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 that have 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.
Do not use for prophylaxis.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals

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 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.
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

People with known hypersensitivity to (fluoro)quinolones should avoid any contact with the product.
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.

4.6 Adverse reactions (frequency and seriousness)

In very rare cases hypersensitivity reactions (allergic skin reactions, anaphylaxis) can occur. In these cases, administration should be discontinued and a symptomatic treatment given.
In very rare cases, possible joint cartilage alterations in growing puppies (see 4.3 contraindications) can be seen. In rare cases vomiting and anorexia are observed.

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

Pregnancy and lactation:
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.

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 anti-inflammatory drugs, convulsions can occur.

4.9 Amounts to be administered and administration route

For oral use.
The dosage is 5 mg enrofloxacin per kg bodyweight once daily.
This is equivalent to 1 tablet per 30 kg bodyweight.

The tablets can be administered directly or with the feed.
Treatment is generally administered over 5 – 10 consecutive days. The recommended dosage should not be exceeded.

Treatment should be re-evaluated if no improvement is seen. It is commonly advised to re-evaluate the treatment if no clinical improvement is observed within 3 days.

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 month.

Do not exceed the recommended dose. In case of overdose, vomiting, diarrhoea and CNS/behavioural changes may occur, this will stop when correct dosing is resumed.

4.11 Withdrawal period(s)

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antibacterials for systemic use, quinolone and quinoxaline antibacterials, fluoroquinolones, enrofloxacin.

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 0.9 µg/mL are reached in dogs.

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 lies between 2 to 7 hours for dogs. Approximately 25% of the dose of enrofloxacin is excreted in the urine and 75% via the faeces. Approximately 60% (dogs) 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
Cellulose, microcrystalline
Povidone (K-30)
Croscarmellose sodium
Silica, colloidal anhydrous
Magnesium stearate
Artificial flavour (beef)

6.2 Major incompatibilities

Not applicable.

6.3 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale: 3 years
Shelf-life of divided tablets after first opening the blister: 2 days

6.4 Special precautions for storage

Return any divided tablet to the opened blister and use within 2 days.

6.5 Nature and composition of immediate packaging

Container material: Aluminium foil blister
Container volume: Cardboard box with 10 and 100 tablets. 10 tablets per blister each.

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

8. MARKETING AUTHORISATION NUMBER

9. DATE OF FIRST AUTHORISATION

10. DATE OF REVISION OF THE TEXT

October 2017

PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable.

Approved: 12/10/2017