A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARTON BOX

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Zobuxa 100 mg tablets for dogs
Enrofloxacin

2. STATEMENT OF ACTIVE SUBSTANCES

One tablet contains: 100 mg Enrofloxacin.

3. PHARMACEUTICAL FORM

Tablet

4. PACKAGE SIZE

1 x 10 tablets

10 x 10 tablets

5. TARGET SPECIES

Dogs

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

<EXP {month/year}>

11. SPECIAL STORAGE CONDITIONS

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

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

Disposal: read package leaflet.

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

Elanco Europe Ltd
Lilly House
Priestley Road
Basingstoke
Hampshire
RG24 9NL

16. MARKETING AUTHORISATION NUMBER

Vm 00879/4026

17. MANUFACTURER'S BATCH NUMBER

<Batch><Lot> {number}

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

ALUMINIUM FOIL BLISTER

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Zobuxa 100 mg tablets for dogs

2. NAME OF THE MARKETING AUTHORISATION HOLDER

Elanco Europe Ltd

3. EXPIRY DATE

<EXP {month/year}>

4. BATCH NUMBER

<Batch><Lot> {number}

5. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET:
Zobuxa 100 mg tablets for dogs
Zobuxa 150 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:
Elanco Europe Ltd
Lilly House
Priestley Road
Basingstoke
Hampshire
RG24 9NL

Manufacturer responsible for batch release:
Elanco France S.A.S.
26 Rue de la Chapelle
68330 Huningue
France

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Zobuxa 100 mg tablets for dogs
Zobuxa 150 mg tablets for dogs
Enrofloxacin

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

One tablet contains:

Active substance:
For 100 mg tablets: Enrofloxacin 100 mg
For 150 mg tablets: Enrofloxacin 150 mg

Excipients:
Lactose monohydrate
Cellulose, microcrystalline
Povidone (K-30)
Croscarmellose sodium
Silica, colloidal anhydrous
Magnesium stearate
Artificial flavor (beef)

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

4. INDICATION(S)

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

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 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.

6. ADVERSE REACTIONS

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 5. 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).

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 use.
The dosage is 5 mg enrofloxacin per kg bodyweight once daily.

For 100 mg tablets: This is equivalent to 1 tablet per 20 kg bodyweight.
For 150 mg tablets: 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.

9. ADVICE ON CORRECT ADMINISTRATION

None.

10. WITHDRAWAL PERIOD(S)

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Return any divided tablet to the opened blister and use within 2 days.
Do not use after the expiry date stated on the carton after EXP.

12. SPECIAL WARNING(S)

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.

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.

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.

Overdose (symptoms, emergency procedures, antidotes):
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.

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

Medicines should not be disposed of via wastewater. Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

Available pack sizes:

Cardboard box with 10 and 100 tablets. 10 tablets per blister each.

Not all pack sizes may be marketed.

To be supplied only on veterinary prescription.

For any information about this veterinary medicinal product, please contact the marketing authorisation holder.

Approved: 12/10/2017