B. PACKAGE LEAFLET

PACKAGE LEAFLET:
Boflox flavour 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

Marketing authorisation holder:
LIVISTO Int'l, S.L.
Av. Universitat Autònoma, 29
08290 Cerdanyola del Vallès (Barcelona)
Spain

Manufacturer responsible for batch release:
aniMedica GmbH
Im Südfeld 9
48308 Senden-Bösensell
Germany

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Boflox flavour 80 mg tablets for dogs
Marbofloxacin

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

Each tablet contains:
Active substance:
Marbofloxacin 80 mg

Oblong beige tablets with brown speckles scored on both sides.

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 or epididymitis
- 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 cases 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 in cats. For the treatment of this species, a divisible 20 mg tablet is available.

6. ADVERSE REACTIONS

At the therapeutic recommended dosage, no severe side-effects are to be expected in dogs. In particular, no lesions of the articular joints were encountered in clinical studies at the recommended dose rate. However, joint pain and/or neurological symptoms (ataxia, aggressiveness, convulsion, depression) may occur on rare occasions.

Allergic reactions have been observed (temporary skin reactions) due to the histamine release that may occur.

Mild 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.

The frequency of adverse reactions is defined using the following convention:
-very common (more than 1 in 10 animals treated displaying adverse reactions during the course of one treatment)
-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.

Alternatively, you can report via your national reporting system {national system details}.

7. TARGET SPECIES

Dog.

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

For oral administration.

The recommended dose rate is 2 mg/kg/d (1 tablet for 40 kg per day) in 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, treatment duration is at least 10 days. 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

None.

10. WITHDRAWAL PERIOD

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

This veterinary medicinal product does not require any special temperature storage conditions.
Store the blisters in the original container.
If the tablets are divided, the remaining halves should be kept in the blister pocket.
Any divided tablet halves remaining after 4 days should be discarded.
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.

12. SPECIAL WARNING(S)

Special warnings for each target species
A low urinary pH could have an inhibitory effect on the activity of marbofloxacin.
Pyoderma occurs mostly secondary to an underlying disease, thus, it is advisable to determine the underlying cause and treat the animal accordingly.

Special 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.

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. Use of the product should be based on susceptibility testing of the bacteria isolated from the animal. If this is not possible, therapy should be based on local (regional, farm level) epidemiological information about susceptibility of the target bacteria. Use of the product deviating from the instructions given in the SPC may increase the prevalence of bacteria resistant to the fluoroquinolones and may reduce effectiveness of treatment with other quinolones due to the potential for cross-resistance.

Official and local antimicrobial policies should be taken into account when the product is used.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
People with known hypersensitivity to (fluoro)quinolones should avoid contact with the veterinary medicinal product.
In case of accidental ingestion seek medical advice immediately and show the package leaflet or the label to the physician. Wash hands after use.

Pregnancy/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.

Interaction with other medicinal products and other forms of interaction:
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 (symptoms, emergency procedures, antidotes):
Overdosage may cause cartilage damage in the joints and acute signs in the form of neurological disorders (e.g. salivation, streaming eyes, shivering, myoclonia, seizures), which should be treated symptomatically.

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 or pharmacist 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

Package sizes:
Box with 6 tablets
Box with 12 tablets
Box with 36 tablets
Box with 72 tablets
Box with 120 tablets
Box with 240 tablets

Not all pack sizes may be marketed.

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