Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Powerflox 50 mg/ml solution for injection for cattle, pigs, dogs and cats
Enrofloxacin.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance:

1 ml of solution for injection contains:

Enrofloxacin	50 mg

Excipient(s):

n-butyl alcohol as antimicrobial preservative	30 mg

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Solution for injection.
Clear yellow solution practically free from particles.

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle, pigs, dogs and cats.

4.2 Indications for use, specifying the target species

Cattle: Treatment of respiratory and alimentary tract diseases of bacterial or mycoplasmal origin (pasteurellosis, mycoplasmosis, coli-bacillosis and coli-septicaemia) and secondary bacterial infections subsequent to viral conditions (e.g. viral pneumonia).

Pigs: Treatment of respiratory and alimentary tract diseases of bacterial or mycoplasmal origin (pasteurellosis, mycoplasmosis, coli-bacillosis and coli-septicaemia) and multifactorial diseases such as enzootic pneumonia.

Dogs and cats: Treatment of bacterial diseases of the respiratory (*Pasteurella* spp., *Haemophilus* spp.), alimentary (*E.coli*., *Salmonella* spp.) and urogenital tracts (*E. coli*), skin and secondary wound infections (*Staphylococcus* spp.).

4.3 Contraindications

Do not use for prophylaxis.
Do not use in case of resistance against quinolones.
Do not use in case of disturbances in growth of cartilages and/or during injury of locomotory system particularly on functionally loaded joints or due to body weight loaded joints.
Do not use in dogs less than 1 year of age or in exceptionally large breeds with a longer growth period under 18 months of age, as articular cartilage may be affected during the period of rapid growth.
Do not use in dogs with CNS disturbances.
Do not use in case of hypersensitivity to the active substance, or to any of the excipients.
Do not use in cats less than 8 weeks of age.

4.4 Special warnings for each target species

Injections in cattle and pig should be administered in the back of the neck.
Cattle: Not more than 10 ml should be administered at one subcutaneous injection site.
Pigs: Not more than 2.5 ml should be administered at one intramuscular injection site.

4.5 Special precautions for use

i) Special precautions for use in animals

Use of the product should be based on susceptibility testing and take into account official and local antimicrobial policies.
Fluoroquinolones should be reseved for the treatment of clinical conditions which have responded poorly, or are expected to respond poorly, to other classes of antimicrobials.
It is prudent to reserve enrofloxacin for the treatment of clinical conditions which have responded poorly to other classes of antimicrobials.
Use of the product deviating from the instructions given in the SPC may increase the prevalence of bacteria resistant to the fluoroquinolones and may decrease the effectiveness of treatment with other quinolones due to potential for cross resistance.
Treatment should not be repeated if an allergic reaction occurs.
Enrofloxacin is partially excreted through the kidney. In the case of the kidney's functional failure slower excretion should be taken into account.
Do not re-inject into the same injection site.
The cap may be safely punctured up to 40 times. When treating groups of animals, use a draw-off needle.
Only the 50 ml vial should be used to treat dogs, cats and small piglets.
Retinotoxic effects including blindness can occur in cat when the recommended dose is exceeded. *These effects have also been reported after administration of therapeutic doses of enrofloxacin in rare cases.*

ii) 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.
Direct contact with the skin should be avoided because of sensitisation, contact dermatitis and possible hypersensitivity reactions. Wear gloves.
This product is an alkaline solution.
Wash any splashes from skin and eyes immediately with water.
Do not eat, drink or smoke whilst using the product.
Care should be taken to avoid accidental self-injection. If accidental injection occurs, seek medical advice immediately.
Wash hands after use.

4.6 Adverse reactions (frequency and seriousness)

Local tissue reactions may occasionally occur at the injection site.
Occasionally skin reactions have been seen after administration in kennelled greyhounds.
In cattle and dogs, gastrointestinal disturbances may occasionally occur.
Administering to young animals in their growth period could cause cartilage lesions in the joints.

4.7 Use during pregnancy, lactation or lay

Do not use in bitches or queens during pregnancy and lactation.

4.8 Interaction with other medicinal products and other forms of interaction

When combined with macrolide antibiotics, tetracyclines and chloramphenicol (dog) enrofloxacin may produce an antagonistic effect.

Theophylline clearance will be reduced.

4.9 Amounts to be administered and administration route

Cattle: 0.5 ml per 10 kg bodyweight (2.5 mg enrofloxacin per kg bodyweight) daily by subcutaneous injection for 5 days. This rate may be doubled (1 ml per 10 kg; 5 mg/kg) for 5 days for complicated respiratory diseases.

Pigs: 0.5 ml per 10 kg bodyweight (2.5 mg enrofloxacin per kg bodyweight) daily by intramuscular injection for 3 days. This rate may be doubled (1 ml per 10 kg; 5 mg/kg) for 3 days for complicated respiratory diseases. (Not more than 2.5 ml should be given at one intramuscular site).

Dogs and cats: 1 ml per 10 kg bodyweight (5 mg enrofloxacin per kg bodyweight) daily by subcutaneous injection for 5 days. For complicated diseases, the treatment period may be prolonged for up to 10 days.

If there is no clinical improvement within two to three days, further susceptibility testing and possibly a change in antimicrobial therapy should be considered.

Do not exceed the recommended dose.
Normal sterile precautions should be taken.
To ensure a correct dosage, body weight should be determined as accurately as possible to avoid underdosing.

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

In target animal studies, cats have been shown to suffer ocular damage after receiving doses of more than 15 mg/kg once daily for 21 consecutive days. Doses of 30 mg/kg given once daily for 21 consecutive days have been shown to cause irreversible ocular damage. At 50 mg/kg given once daily for 21 consecutive days, blindness can occur.
Do not exceed the recommended dose. In accidental overdose there is no antidote and treatment should be symptomatic.

4.11 Withdrawal Period(s)

Cattle: Meat and offal: 14 days
Pigs: Meat and offal: 10 days

Not permitted for use in lactating animals producing milk for human consumption.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Enrofloxacin is an antiinfective for systemic use belonging to the group of fluoroquinolones.

ATCvet code: QJ01MA90

5.1 Pharmacodynamic properties

Enrofloxacin is a synthetic, broad spectrum antimicrobial, bactericidal in action and effective against a wide range of gram positive and gram negative bacteria as well as mycoplasmas. It inhibits the enzyme DNA-gyrase in the cell nuclei during replication of bacterial DNA. It also acts on bacterial cells during stationary phase by changing the permeability in the phospholipid cellular membranes.

Bacterial resistance to fluoroquinolones most commonly occurs by alteration of the target, DNA-gyrase, via mutation. Less commonly mutation occurs at the topoisomerase-IV target. Other mechanisms of resistance occur when bacteria decrease the ability of the drug to enter the cell or increase active transport out of the cell. Resistance is usually chromosomally developed and, therefore, remains after antimicrobial therapy ends. Cross-resistance of enrofloxacin with other fluoroquinolones can occur. Changes in levels of resistance to fluoroquinolones over time by Campylobacter and Salmonella species are being monitored because of their possible impact on human health.

5.2 Pharmacokinetic properties

The pharmacokinetics of enrofloxacin are such that both oral and parenteral administration lead to similar serum levels. Enrofloxacin possesses a high distribution volume. Tissue levels 2 - 3 times higher than that found in the serum have been demonstrated in laboratory animals and target species. Organs in which high levels can be expected are the lungs, liver, kidney, bone and lymphatic system.
Enrofloxacin also distributes into the cerebrospinal fluid, the aqueous humour and the foetus in pregnant animals.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

n-butyl alcohol
Potassium hydroxide
Water for injections

6.2 Incompatibilities

None known.

6.3 Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale: 5 years
Shelf-life after first opening the immediate packaging: 28 days

6.4 Special precautions for storage

Do not store above 25°C.
Keep the vial in the outer carton in order to protect from light.

6.5 Nature and composition of immediate packaging

Cardboard box with 1 amber Type I glass vial of 50 or 100 ml with a grey bromobutyl rubber stopper and aluminium cap.
Cardboard box with 1 amber Type II glass vial of 50 or 100 ml with a grey bromobutyl rubber stopper and aluminium cap.
Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials

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

7 MARKETING AUTHORISATION HOLDER

Virbac S.A.
1ère avenue
2065 m L.I.D.
06516 Carros Cedex
France

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10988/071/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 10th July 2009

Date of last renewal: 10th July 2014

10 DATE OF REVISION OF THE TEXT