

Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Powerflox 100 mg/ml solution for injection for cattle and pigs
Enrofloxacin.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance:

1 ml of solution for injection contains:

Enrofloxacin	100 mg
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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 and pigs.

4.2 Indications for use, specifying the target species

Cattle: diseases of the respiratory and alimentary tract of bacterial or mycoplasmal origin (e.g. pasteurellosis, mycoplasmosis, coli-bacillosis and coli-septicaemia) and secondary bacterial infections subsequent to viral infections (e.g. viral pneumonia) where clinical experience, supported where possible by sensitivity testing of the causal organism, indicates enrofloxacin as the drug of choice.

Treatment of local signs (inflammation, milk quality and yield) associated with peracute/acute mastitis in lactating dairy cattle caused by E. coli, where herd history and previous sensitivity testing indicate enrofloxacin as the drug of choice.

Pigs: Diseases of the respiratory and alimentary tract of bacterial or mycoplasmal origin (pasteurellosis, mycoplasmosis, coli-bacillosis and coli-septicaemia) and multifactorial diseases such as enzootic pneumonia where clinical experience, supported where possible by sensitivity testing of the causal organism, indicates enrofloxacin as the drug of choice.

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 case of hypersensitivity to the active substance, or to any of the excipients.

4.4 Special warnings for each target species

Cattle: Not more than 10 ml should be administered at one subcutaneous injection site.

Calves: Not more than 5 ml should be administered at one subcutaneous injection site.

Pigs: Not more than 2.5 ml should be administered at one intramuscular injection site.

Injections should be administered in the back of the neck.

4.5 Special precautions for use

i) Special precautions for use in animals

The safety of the product has not been established in pigs or calves when administered by the intravenous route and use of this route of administration is not recommended in these animal groups.

Use of the product should be based on susceptibility testing and take into account official and local antimicrobial policies.

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.

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 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 small piglets.

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.

In cattle, gastrointestinal disturbances may occasionally occur.

4.7 Use during pregnancy, lactation or lay

Enrofloxacin can be used during pregnancy and lactation.

4.8 Interaction with other medicinal products and other forms of interaction

When combined with tetracyclines and macrolide antibiotics, enrofloxacin may produce an antagonistic effect.

4.9 Amounts to be administered and administration route

Cattle:

For respiratory and alimentary infections in cattle and secondary bacterial infections: administer by subcutaneous injection.

- 2.5 ml per 100 kg bodyweight (2.5 mg enrofloxacin per kg bodyweight) daily by subcutaneous injection for 3 days. This rate may be doubled (5 ml per 100 kg; 5 mg/kg) for 5 days for complicated respiratory disease.

For E. Coli mastitis: administer by slow intravenous injection.

- 5.0 ml per 100 kg bodyweight (5 mg enrofloxacin per kg bodyweight) daily for 2 days.

Pigs:

2.5 ml per 100 kg bodyweight (2.5 mg enrofloxacin per kg bodyweight) daily by intramuscular injection for 3 days.

This rate may be doubled (5 ml per 100 kg; 5 mg/kg) for

3 days for complicated respiratory disease. (Not more than 2.5 ml should be given at one intramuscular site).

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

Do not exceed the recommended dose. In accidental overdose there is no antidote and treatment should be symptomatic.

4.11 Withdrawal Period(s)

Cattle: Subcutaneous use

Meat and offal: 14 days

Milk: 96 hours (8 milkings)

Cattle: Intravenous use

Meat and offal: 4 days

Milk: 72 hours (6 milkings)

Pigs: Intramuscular use

Meat and offal: 10 days

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Enrofloxacin is an anti-infective 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 10988/071/002

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