Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Fenoflox 50 mg/ml Solution for Injection for Cattle, Pigs, Dogs and Cats.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:

Enrofloxacin	50 mg

Excipient:

n-butanol	30 mg

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Solution for injection.

Clear light yellow solution free from particulate matter.

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle (calves), Pigs, Dogs and Cats.

4.2 Indications for use, specifying the target species

Calves:
Treatment of infections of respiratory tract caused by enrofloxacin susceptible strains of *Pasteurella multocida, Mannheimia haemolytica* and *Mycoplasma* spp.
Treatment of infections of the alimentary tract caused by enrofloxacin susceptible strains of *Escherichia coli*.
Treatment of septicaemia caused by enrofloxacin susceptible strains of *Escherichia coli*.
Treatment of acute mycoplasma-associated arthritis due to enrofloxacin susceptible strains of *Mycoplasma bovis.*
Pigs:
Treatment of infections of the respiratory tract caused by enrofloxacin susceptible strains of *Pasteurella multocida, Mycoplasma* spp. and *Actinobacillus pleuropneumoniae.*
Treatment of infections of the alimentary tract caused by enrofloxacin susceptible strains of *Escherichia coli.*
Treatment of septicaemia caused by enrofloxacin susceptible strains of *Escherichia coli.*
Dogs:
Treatment of infections of the alimentary, respiratory and urogenital tracts (including prostatitis, adjunctive antibiotic therapy for pyometra), skin and wound infections and otitis (externa/media) caused by enrofloxacin susceptible strains of *Staphylococcus* spp., *Escherichia coli, Pasteurella* spp., *Klebsiella* spp., *Bordetella* spp., *Pseudomonas* spp. and *Proteus* spp.
Cats:
Treatment of infections of the alimentary, respiratory and urogenital tracts (as adjunctive antibiotic therapy for pyometra), skin and wound infections, caused by enrofloxacin susceptible strains of, e.g.: *Staphylococcus* spp., *Escherichia coli, Pasteurella* spp., *Klebsiella* spp., *Bordetella* spp., *Pseudomonas* spp. and *Proteus* spp.

4.3 Contraindications

Do not use when resistance / cross resistance to (Fluoro)quinolones is known to occur. Refer to section 4.5. Do not use in the case of known hypersensitivity to fluoroquinolones or to any of the excipients.
Dogs under 1 year of age should not be treated with Enrofloxacin as damage to the articular cartilage may occur during the period of rapid growth, specifically in large breeds of dog. As a precaution very large breeds of dog should not be treated with Enrofloxacin until they are 18 months of age because of their longer growth period.
Do not use in cats less than 8 weeks of age.
Do not use for prophylaxis.
Do not use in growing horses because of possible deleterious damage on articular cartilage.

4.4 Special warnings for each target species

Cattle (calves), pigs:
None
Cats:
Retinotoxic effects including blindness can occur when the recommended dose is exceeded.
Dogs:
Occasionally skin reactions have been seen after administration to kennelled greyhounds.

4.5 Special precautions for use

Special precautions for use in animals
Do not exceed the recommended dosage.
Repeat injections should be made at different sites.
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 the fluoroquinolones and may decrease the effectiveness of treatment with other quinolones due to the potential for cross resistance.
Enrofloxacin should be used with caution in epileptic animals or animals affected by renal dysfunction.
Degenerative changes of articular cartilage were observed in calves treated orally with 30 mg enrofloxacin/kg bw during 14 days.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
The product is an alkaline solution. Wash any splashes from skin and eyes immediately with water. Direct contact with the skin should be avoided because of sensitisation, contact dermatitis and possible hypersensitivity reactions. Wear gloves. Do not eat, drink or smoke whilst using the product. Care should be taken to avoid accidental self-injection. In case of accidental injection, seek medical advice immediately and show the package leaflet or the label to the physician.

4.6 Adverse reactions (frequency and seriousness)

During the period of rapid growth, enrofloxacin may affect articular cartilage.

Local tissue reactions may occasionally occur at the injection site.

Normal sterile precautions should be taken.

In cattle and dogs, gastrointestinal disturbances may occasionally occur.

4.7 Use during pregnancy, lactation or lay

There is no restriction on the use of this product during pregnancy and lactation.

4.8 Interaction with other medicinal products and other forms of interaction

Combination of enrofloxacin with cloramphenicol, macrolide antibiotics or tetracyclines may produce antagonistic effects.

Enrofloxacin may interfere with the metabolism of theophylline, decreasing theophylline clearance resulting in increased plasma levels of theophylline.

Care should be taken during the concomitant use of flunixin and enrofloxacin in dogs to avoid adverse drug reactions. The decrease in drug clearances as a result of co-administration of flunixin and enrofloxacin indicates that these substances interact during the elimination phase. Thus, in dogs, the co-administration of enrofloxacin and flunixin increased the AUC and the elimination half-life of flunixin and increased the elimination half-life and reduced the C_{max} of enrofloxacin.

4.9 Amounts to be administered and administration route

Intravenous, subcutaneous or intramuscular use.
Repeated injections should be made at different injection sites.
To ensure a correct dosage, body weight (bw) should be determined as accurately as possible to avoid underdosing.
Calves:
5 mg of enrofloxacin/kg bw, corresponding to 1 ml/10 kg bw, once daily for 3-5 days.
Acute mycoplasma-associated arthritis due to enrofloxacin susceptible strains of *Mycoplasma bovis:* 5 mg of enrofloxacin/kg bw, corresponding to 1 ml/10 kg bw, once daily for 5 days.
The product can be administered by slow intravenous or subcutaneous administration.
Not more than 10 ml should be administered at the one subcutaneous injection site.

Pigs:
2.5 mg enrofloxacin per kg bodyweight (corresponding to 0.5 ml/10 kg bw) once daily by intramuscular injection for 3 days.
Alimentary tract infection or septicaemia caused by *Escherichia coli*: 5 mg of enrofloxacin/kg bw, corresponding to 1 ml/10 kg bw, once daily by intramuscular injection for 3 days.
In pigs, the injection should be made in the neck at the ear base.
Not more than 3 ml should be administered at one intramuscular injection site.

Dogs and Cats:
5 mg of enrofloxacin per kg bodyweight (corresponding to 1 ml/10 kg bw) daily by subcutaneous injection for up to 5 days.
Treatment may be initiated with injectable product and maintained with enrofloxacin tablets. Duration of treatment should be based on the duration of treatment approved for the appropriate indication in the SPC of the tablet product.

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

In dogs and cats, lack of appetite and nausea may occur following overdose.
Overdose may result in CNS and renal dysfunction. In dogs, 10-fold over dosage results in neurological symptoms such as ataxia, tremor, nystagmus or convulsions. These symptoms are reversible on cessation of treatment.
No signs of over dosage were observed in pigs following administration of the product at five times the recommended therapeutic dose.
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.
In accidental overdose, there is no antidote and treatment should be symptomatic.

4.11 Withdrawal Period(s)

Calves:
Following intravenous injection: Meat and offal: 5 days.
Following subcutaneous injection: Meat and offal: 12 days.
Not authorised for use in animals producing milk for human consumption.
Pigs:
Meat and offal: 13 days.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: antibacterials for systemic use, fluoroquinolones.
ATC Vet Code: QJ01MA90

5.1 Pharmacodynamic properties

Mode of action
Two enzymes essential in DNA replication and transcription, DNA gyrase and topoisomerase IV, have been identified as the molecular targets of fluoroquinolones. Target inhibition is caused by non-covalent binding of fluoroquinolone molecules to these enzymes. Replication forks and translational complexes cannot proceed beyond such enzyme-DNA-fluoroquinolone complexes, and inhibition of DNA and mRNA synthesis triggers events resulting in a rapid, drug concentration-dependent killing of pathogenic bacteria. The mode of action of enrofloxacin is bactericidal and bactericidal activity is concentration dependent.

Antibacterial spectrum
Enrofloxacin is active against many Gram-negative bacteria such as *Escherichia coli*, *Klebsiella* spp., *Actinobacillus pleuropneumoniae, Mannheimia haemolytica*, *Pasteurella* spp. (e.g. *Pasteurella multocida*), *Bordetella* spp., *Proteus* spp., *Pseudomonas* spp., against Gram-positive bacteria such as *Staphylococcus* spp. (e.g. *Staphylococcus aureus*) and against *Mycoplasma* spp. at the recommended therapeutic doses.

Types and mechanisms of resistance
Resistance to fluoroquinolones has been reported to arise from five sources, (i) point mutations in the genes encoding for DNA gyrase and/or topoisomerase IV leading to alterations of the respective enzyme, (ii) alterations of drug permeability in Gram-negative bacteria, (iii) efflux mechanisms, (iv) plasmid mediated resistance and (v) gyrase protecting proteins. All mechanisms lead to a reduced susceptibility of the bacteria to fluoroquinolones. Cross-resistance within the fluoroquinolone class of antimicrobials is common.

5.2 Pharmacokinetic properties

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, skin, 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-butanol,
Potassium hydroxide, (for pH adjustment)
Water for injections

6.2 Incompatibilities

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

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.
After first opening the immediate packaging: do not store above 25°C.

6.5 Nature and composition of immediate packaging

Container material:	Type I Amber Glass
Container closure:	Grey teflonised chlorobutyl rubber stopper with an aluminium cap
Container colour:	Amber
Container volumes:	100 ml, 250 ml

No. of containers in a carton:
1 x 100 ml, 5 x 100 ml, 10 x 100 ml, 12 x 100 ml, 15 x 100 ml, 20 x 100 ml
1 x 250 ml, 5 x 250 ml, 10 x 250 ml, 12 x 250 ml, 15 x 250 ml, 20 x 250 ml.

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 product should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

Chanelle Pharmaceuticals Manufacturing Ltd.,
Loughrea,
Co. Galway,
Ireland.

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10987/072/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 14th May 2010
Date of last renewal: 21st August 2015

10 DATE OF REVISION OF THE TEXT

August 2015