Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Baytril Max 100 mg/ml Solution for Injection for Cattle.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active constituents	mg/ml
Enrofloxacin	100
Relevant constituents of the Excipinets	
Benzyl alcohol	20
n-butyl alcohol	30

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Solution for injection.
Clear yellow sterile aqueous solution

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle.

4.2 Indications for use, specifying the target species

Indicated for the treatment of bovine respiratory disease associated with *Mannheimia haemolytica, Pasteurella multocida, Haemophilus somnus* and *Mycoplasma* spp. where clinical experience, supported where possible by sensitivity testing of the causal organism, indicates enrofloxacin as the drug of choice.

4.3 Contraindications

Baytril Max should not be used for prophylaxis.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals:
Normal sterile precautions should be taken.
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, fluoroquinoones 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.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Baytril Max is an alkaline solution. Wash any splashes from skin or 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 self injection occurs seek medical advice immediately.

4.6 Adverse reactions (frequency and seriousness)

Transient local reactions may occur at injection site.

4.7 Use during pregnancy, lactation or lay

No restriction (see 4.11)

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

Dosage and duration of treatment
A single dose of 7.5 mg/kg bodyweight (7.5 ml per 100 kg bodyweight)

Method of administration
Baytril Max is administered subcutaneously.

Not more than 15 ml should be administered at one subcutaneous injection site.

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

A dose of 25 mg/kg bodyweight administered for 15 consecutive days is tolerated without any clinical symptoms.

Clinical signs seen in gross overdosage include lethargy, lameness, ataxia, slight salivation and muscle tremors. In accidental overdose there is no antidote and treatment should be symptomatic.

4.11 Withdrawal Period(s)

Meat and offal: 14 days

Milk: 84 hours - Milk may only be taken from cattle from 84 hours (i.e. at the 7^{th} milking in cows milked 12 hourly) following the last treatment.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Enrofloxacin is a synthetic, broad spectrum antimicrobial substance, belonging to the fluoroquinolone group of antibiotics.

ATC Vet Code: QJ01 MA90

5.1 Pharmacodynamic properties

It is bactericidal in action with activity against many Gram positive and Gram negative bacteria and mycoplasmas. The mechanism of action of the quinolones is unique among antimicrobials - they act primarily to inhibit bacterial DNA gyrase, an enzyme responsible for controlling the supercoiling of bacterial DNA during replication. Resealing of the double stranded helix is inhibited resulting in irreversible degradation of the chromosomal DNA. The fluoroquinolones also possess activity against bacteria in the stationary phase by an alteration of the permeability of the outer membrane phospholipid cell wall but are inactive against strict anaerobes.

5.2 Pharmacokinetic properties

The pharmacokinetics of enrofloxacin are such that oral and parenteral administration leads to similar serum levels. Enrofloxacin is lipid soluble and amphoteric and 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.

After subcutaneous administration of 7.5 mg/kg the mean peak plasma concentration is 0.8 microgram/ml achieved within 6 hours. Enrofloxacin is partly metabolised in the liver. Approximately 45 per cent of the dose is excreted in the urine and 55 per cent in the faeces as active and metabolites

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Benzyl alcohol
Arginine
n-butyl alcohol
Water for injections

6.2 Incompatibilities

None known.

6.3 Shelf-life

Shelf-life of the product as packaged for sale: 3 years

Shelf-life after first opening the container: Following withdrawal of the first dose, use the product within 28 days. Discard if visibly contaminated

6.4 Special precautions for storage

Do not store above 25°C. Do not freeze.

6.5 Nature and composition of immediate packaging

Container material:	Type I glass
Container closure:	Siliconised grey rubber butyl stopper
Container colour:	Amber
Container volume:	100 ml

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

Any unused product or waste material should be disposed of in accordance with national requirements.

7 MARKETING AUTHORISATION HOLDER

Bayer Limited,
Animal Health Division,
The Atrium,
Blackthorn Road,
Dublin 18

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10021/037/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

20th December 2008

10 DATE OF REVISION OF THE TEXT

5th December 2011