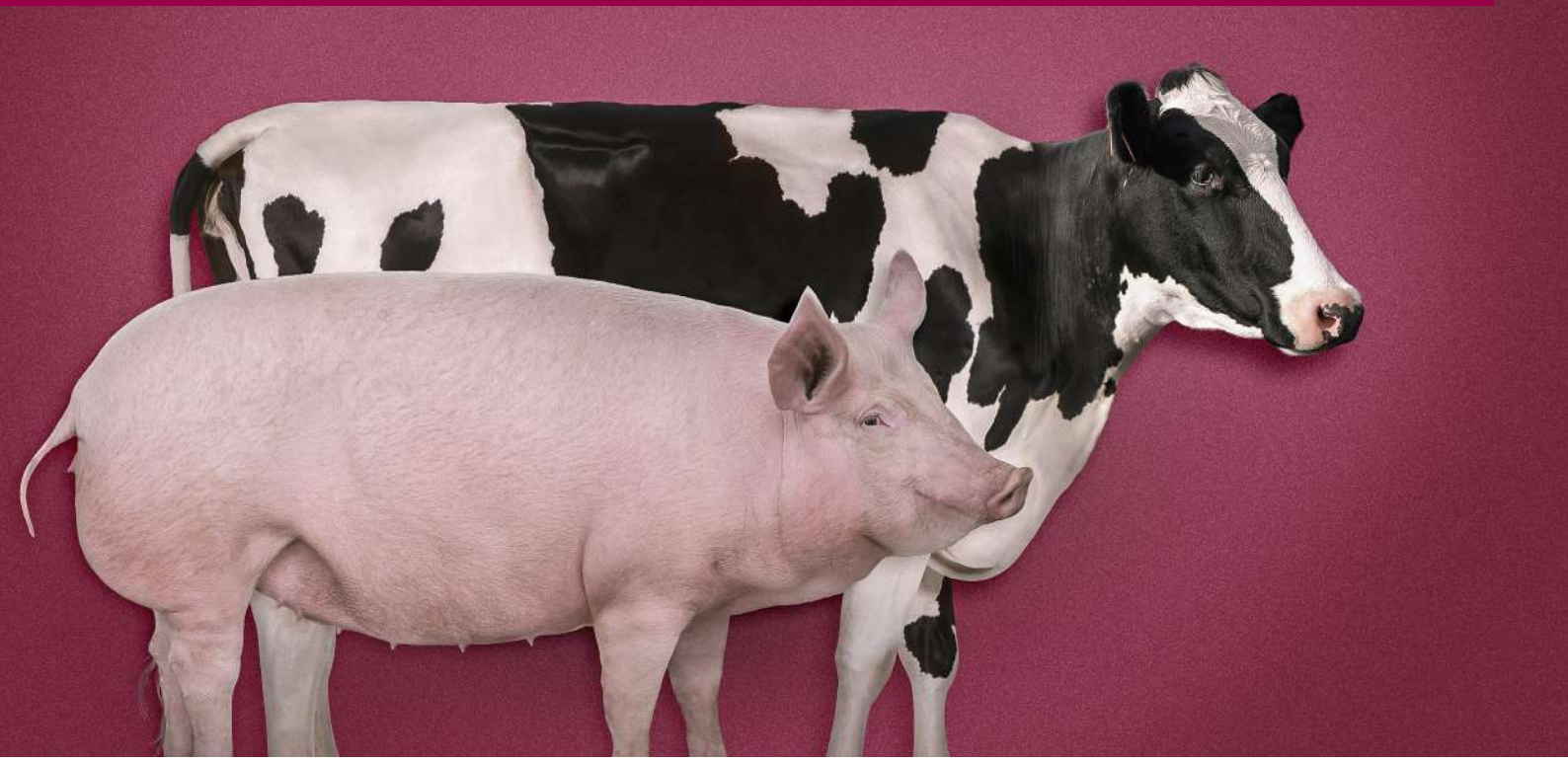
UNISOL

100 MG/ML SOLUTION FOR INJECTION FOR CATTLE AND PIGS

Enrofloxacin 100mg/ml

DATA SHEET



INDICATIONS FOR USE

Cattle

Treatment of infections of the respiratory tract caused by enrofloxacin susceptible strains of *Pasteurella multocida*, *Mannheimia haemolytica* and *Mycoplasma* spp.
Treatment of acute severe mastitis caused by enrofloxacin susceptible strains of Escherichia coli.
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* in cattle less than 2 years old.

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 urinary tract caused by enrofloxacin susceptible strains of *Escherichia coli*.
Treatment of post-partum dysgalactiae syndrome, PDS (MMA syndrome) caused by enrofloxacin susceptible strains of *Escherichia coli* and *Klebsiella* 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*.

LIST No	UNIT PACKAGE	CASE SIZE
1UNI001	100 ml	12

See reverse for Administration & Dosage

BENEFITS

- **Broad spectrum injectable antibiotic for use in cattle and pigs**
- **Can be given via subcutaneous, intramuscular and intravenous routes**
- **Wide range of indications for use**

UNISOL

100 mg/ml solution for injection for cattle and pigs

Enrofloxacin 100mg/ml

ACTIVE SUBSTANCE
Enrofloxacin 100.0 mg/ml
Solution for injection. Clear slightly yellowish solution.

TARGET SPECIES
Cattle and pigs

INDICATIONS FOR USE
Cattle
Treatment of infections of the respiratory tract caused by enrofloxacin susceptible strains of *Pasteurella multocida*, *Mannheimia haemolytica* and *Mycoplasma* spp.
Treatment of acute severe mastitis caused by enrofloxacin susceptible strains of *Escherichia coli*.
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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 urinary tract caused by enrofloxacin susceptible strains of *Escherichia coli*.
Treatment of post-partum dysgalactiae syndrome, PDS (MMA syndrome) caused by enrofloxacin susceptible strains of *Escherichia coli* and *Klebsiella* 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*.

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 should be determined as accurately as possible to avoid underdosing.
Cattle:
5 mg of enrofloxacin/kg bw, corresponding to 1 ml/20 kg bw, once daily for 3-5 days.
Acute mycoplasma-associated arthritis due to enrofloxacin susceptible strains of Mycoplasma bovis in cattle less than 2 years old: 5 mg of enrofloxacin/kg bw, corresponding to 1 ml/20 kg bw, once daily for 5 days. The product can be administered by slow intravenous or subcutaneous administration.
Acute mastitis caused by Escherichia coli: 5 mg enrofloxacin/kg bw, corresponding to 1 ml/20 kg bw, by slow intravenous injection once daily for two consecutive days.
The second dose may be administered by the subcutaneous route. In this case, the withdrawal period following subcutaneous injection applies.
Not more than 10 ml should be administered at any one subcutaneous injection site.
Pigs:
2.5 mg of enrofloxacin/kg bw, corresponding to 0.5 ml/20 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/20 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.
The stopper should not be punctured more than 20 times.

WITHDRAWAL PERIODS
Cattle:
Following intravenous injection:
Meat and offal: 5 days
Milk: 3 days
Following subcutaneous injection:
Meat and offal: 12 days
Milk: 4 days
Pigs:
Meat and offal: 13 days

CONTRAINDICATIONS
Do not use in growing horses because of possible deleterious damage on articular cartilage. Do not use for prophylaxis. Do not use when resistance / cross resistance to (Fluoro)quinolones is known to occur. Do not use in the case of known hypersensitivity to the active substance, to other (fluoro) quinolones or to any of the excipients.

SPECIAL WARNINGS FOR EACH TARGET SPECIES
None known.

SPECIAL PRECAUTIONS FOR USE IN ANIMALS
Degenerative changes of articular cartilage were observed in calves treated orally with 30 mg enrofloxacin/kg bodyweight for 14 days. Do not exceed the recommended dose.
Repeat injections should be administered at different sites.
Enrofloxacin should be used with caution in epileptic animals or animals affected by renal dysfunction.
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.
The use of enrofloxacin in growing lambs at the recommended dose for 15 days caused histological changes in the articular cartilage, not associated with clinical signs.

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 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 and show the package leaflet or the label to the physician.
People with known hypersensitivity to fluoroquinolones should avoid contact with the product.
Direct contact with the skin should be avoided because of sensitisation, contact dermatitis and possible hypersensitivity reactions. Wear gloves.

ADVERSE REACTIONS
Local tissue reactions may occasionally occur at the injection site. Normal sterile precautions should be taken.
In cattle, gastrointestinal disturbances may occasionally occur.

USE DURING PREGNANCY OR LACTATION
There is no restriction on the use of this product during pregnancy and lactation.

INTERACTION WITH OTHER MEDICINAL PRODUCTS
Antagonistic effects due to concurrent administration of bacteriostatic antimicrobial agents such as macrolides or tetracyclines and phenicols may occur.

OVERDOSE
Do not exceed the recommended dose. In accidental overdose (lethargy, anorexia) there is no antidote and treatment should be symptomatic.
No signs of over dosage were observed in pigs following administration of the product at five times the recommended therapeutic dose.

PHARMACODYNAMIC PROPERTIES
Pharmacotherapeutic group: antibiotics, fluoroquinolone group.
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. They modulate the topological state of DNA through cleaving and resealing reactions. Initially, both strands of the DNA double helix are cleaved. Then, a distant segment of DNA is passed through this break before the strands are resealed. Target inhibition is caused by non-covalent binding of fluoroquinolone molecules to an intermediate state in this sequence of reactions, in which DNA is cleaved, but both strands are retained covalently attached to the 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.
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*), 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.

PHARMACOKINETIC PROPERTIES
Enrofloxacin possesses a high distribution volume. Tissue levels 2-3 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.

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

SHELF-LIFE
Shelf life of the veterinary medicinal product as packaged for sale: 2 years
Shelf life after first opening the immediate packaging: 28 days

SPECIAL PRECAUTIONS FOR STORAGE
Protect from light. Do not freeze.

SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED VETERINARY MEDICINAL PRODUCTS
Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

MARKETING AUTHORISATION HOLDER
VETPHARMA ANIMAL HEALTH, S.L.
Les Corts, 23
08028 – Barcelona, SPAIN

DISTRIBUTED BY
Bimeda Animal Health Limited
2, 3 & 4 Airton Close, Airton Road
Tallaght, Dublin 24
Ireland

MARKETING AUTHORISATION NUMBER
VPA 10516/001/001

LEGAL CATEGORY
POM

TAKE TIME OBSERVE LABEL DIRECTIONS

www.bimeda.ie

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