

# UNISOL

100 mg/ml solution for injection for cattle and pigs

**Enrofloxacin 100mg/ml**

## INDICATIONS

Treatment of bacterial infections caused by strains susceptible to enrofloxacin.

## BENEFITS

- Enrofloxacin is a potent member of the fluoroquinolone family
- Bactericidal antibiotic
- Active against wide range of gram positive and gram negative bacteria and mycoplasmas
- Injection rate may be doubled for complicated disease



## PACKAGING

LIST NO.	UNIT PACKAGE	CASE SIZE
1UNI001	100ml	12

Bimeda<sup>®</sup>  
 Broomhill Road, Tallaght  
 Dublin 24, Ireland  
 Tel: 1850-515253 Fax: 01 451 5803

See reverse side for Administration and Dosage.



Bryn Cefni Industrial Park, Llangefni, Anglesey,  
 Wales, LL777XA UK +44 (0) 800 526769

[www.bimeda.com](http://www.bimeda.com)

## UNISOL

### 100 mg/ml solution for injection for cattle and pigs

#### CATTLE

- Respiratory infections caused by *Pasteurella* spp. or *Mycoplasma* spp.
- Alimentary tract infections caused by *E. coli*.

#### PIGS

- Respiratory infections caused by of *Pasteurella* spp. or *Mycoplasma* spp.
- Alimentary tract infections caused by *E. coli*.
- Enrofloxacin should be used where clinical experience, supported where possible by sensitivity testing of the causal organism, indicates enrofloxacin as the drug of choice.

#### PRESENTATION

Solution for injection

Clear slightly yellowish solution

Each 1 ml of solution contains:

##### Active Constituents

Enrofloxacin 100.0 mg

##### Relevant Constituents of the Excipients

Benzyl alcohol 7.8mg

Disodium edetate 10.0mg

#### LIST OF EXCIPIENTS

- Benzyl alcohol
- Disodium edetate
- Potassium hydroxide
- Glacial acetic acid
- Water for injections

#### USES

For the treatment of diseases in cattle and pigs involving organisms sensitive to Enrofloxacin, including Respiratory infections caused by *Pasteurella* spp. or *Mycoplasma* spp. alimentary tract infections caused by *E. coli*.

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.

#### DOSAGE AND ADMINISTRATION

Administration sub-cutaneous or intramuscular (IM) route. To ensure correct dosage, body weight should be determined as accurately as possible to avoid underdosing.

##### Cattle:

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

- 2.5 mg enrofloxacin per kg bodyweight daily by subcutaneous injection for 3 days (2.5 ml per 100 kg bodyweight). This rate may be doubled to 5 mg/kg bodyweight (5 ml per 100 kg) for 5 days for complicated respiratory disease.
- Not more than 10 ml should be administered at any one subcutaneous injection site.

##### Pigs:

**For respiratory and alimentary infections in pigs and secondary bacterial infections:** administer by intramuscular injection.

- 2.5 mg enrofloxacin per kg bodyweight daily by intramuscular injection for 3 days (2.5 ml per 100 kg bodyweight). This rate may be doubled to 5 mg/kg bodyweight (5 ml per 100 kg) for 5 days for complicated respiratory disease.
- Not more than 2.5 ml should be administered at any one intramuscular injection site.
- The stopper should not be punctured more than 20 times.

#### CONTRAINDICATIONS AND WARNINGS

##### 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.
- **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.

#### 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.
- Direct contact with the skin should be avoided because of sensitisation, contact dermatitis and possible hypersensitivity reactions. Wear gloves.

#### ADVERSE REACTIONS (FREQUENCY AND SERIOUSNESS)

- Local tissue reactions may occasionally occur at the injection site. Normal sterile precautions should be taken.

- Rarely, anaphylactic reactions may occur following intravenous administration.
- In cattle, gastrointestinal disturbances may occasionally occur.

#### USE DURING PREGNANCY, LACTATION OR LAY

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

#### INTERACTION WITH OTHER MEDICINAL PRODUCTS AND OTHER FORMS OF INTERACTION

Antagonistic effects due to concurrent administration of macrolides, and tetracyclines may occur. Enrofloxacin may interfere with the metabolism of theophylline, decreasing theophylline clearance resulting in increased plasma levels of theophylline.

#### WITHDRAWAL PERIODS

##### Cattle: Subcutaneous Use

Meat and offal: 13 days

Milk: 84 hours

##### Pigs: Intramuscular Use

Meat and offal: 10 days

#### PHARMACEUTICAL PRECAUTIONS:

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 PRODUCT OR WASTE DERIVED FROM THE USE OF SUCH PRODUCTS

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

#### LEGAL CATEGORY:

Ireland POM

UK POM-V

**PACKAGE QUANTITIES:** Multi-dose glass vials

#### MARKETING AUTHORISATION HOLDER:

Bimeda Chemicals Ltd.,  
A division of Cross Vetpharm Group Ltd.,  
Broomhill Road, Tallaght, Dublin 24, Ireland.

#### MARKETING AUTHORISATION NUMBER:

VPA no. 10516/001/001

VM no. 32509/4005

