ENCURE-10 INJECTION
(Enrofloxacin)

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

ENCURE-10 INJECTION

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 100ml Contains:
Enrofloxacin …….…. 10gm

3. PHARMACEUTICAL FORM

Solution for injection.

4. CLINICAL INFORMATION

4.1. Target species

Cattle, Sheep & Goats.

4.2. Indications for use specifying the target species

Cattle, Sheep and Goat:
Treatment of infections of the respiratory tract caused by enrofloxacin susceptible strains of Pasteurella multocida, Mannheimia haemolytica, Staphylococcus aureus 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.

4.3. Contraindications

Do not use in animals with known hypersensitivity to enrofloxacin or other fluoroquinolones or to any of the excipients.
Do not use in growing horses because of possible deleterious damage on articular cartilage.

4.4. Special warnings for each target species

None.

4.5. Special precautions for use

Special precautions for safe use in the target species:

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 including use deviating from the instructions given in the
SPC may increase the prevalence of bacteria resistant to enrofloxacin and may decrease the effectiveness of treatment with all fluoroquinolones due to the potential for cross-resistance. Degenerative changes of articular cartilage were observed in calves treated orally with 30 mg enrofloxacin/kg body weight during 14 days.
The use of enrofloxacin in growing lambs at the recommended dose for 15 days caused histological changes in the articular cartilage, not associated to clinical signs.

Special precautions to be taken by the person administering the product to animals:

Enrofloxacin may cause hypersensitivity (allergic reactions). People with known hypersensitivity to fluoroquinolones (e.g., enrofloxacin or ciprofloxacin) should avoid any contact with the product.
The product may be irritating to skin and eyes. In case of contact with skin or eyes, wash the affected area with clear running water.
Wash hands after use. Do not eat, drink or smoke whilst handling the product.
Care should be taken to avoid accidental self-injection. If accidental self-injection occurs seek medical advice immediately.

iii) Other precautions
In countries where feeding of fallen stock to scavenger bird populations is permitted as a conservation measure (see Commission Decision 2003/322/EC), the possible risk to hatching success should be considere before feeding carcasses of livestock recently treated with this product.

4.6. Adverse reactions (frequency and seriousness)

Digestive tract disorders (e.g. diarrhoea) may occur in very rare cases. These signs are generally mild and transient.
In very rare cases intravenous treatment of cattle can cause shock reactions, presumably as a result of circulatory impairment.
In very rare cases, neurological signs (seizures, tremors, ataxia, and excitation) and anaphylactic reactions can also occur.

4.7. Use during pregnancy and lactation or lay

Cattle
The safety of the veterinary medicinal product has been established in pregnant cows during the 1st quarter of pregnancy. The product can be used in pregnant cows during the 1st quarter of pregnancy. The use of the product in cows during the 3 last quarters of pregnancy should be based on a benefit-risk assessment by the responsible veterinarian. The product can be used in cows during lactation.

Sheep and goats
The safety of the veterinary medicinal product has not been established during pregnancy and lactation. Use only accordingly to the benefit-risk assessment by the responsible veterinarian.

4.8. Interaction with other veterinary medicinal products and other forms of interaction

Do not use enrofloxacin concomitantly with antimicrobial substances acting antagonistically to quinolones (e.g. macrolides, tetracyclines or phenicols).
Do not use concurrently with theophylline as the elimination of theophylline may be delayed.

4.9. Dosage and administration route

Intravenous or subcutaneous use.

Cattle:
5 mg of enrofloxacin/kg bw, corresponding to 1 ml/20 kg bw, once daily for 3–5 days.
Not more than 10 ml should be administered at one by slow intravenous or subcutaneous injection site.

Sheep and goats:
5 mg of enrofloxacin/kg bw, corresponding to 1 ml/20 kg bw, once daily by subcutaneous injection for 3 days.
Not more than 6 ml should be administered at one subcutaneous injection site.

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

In cases of accidental overdoses digestive tract disorders (e.g. vomiting, diarrhoea) and neurological disorders may occur.
In cattle, sheep and goat, overdose has not been documented.
In accidental overdose there is no antidote and treatment should be symptomatic.

4.11. Withdrawal period:

Cattle:
Following intravenous injection:
Meat and offal: 5 days.
Milk: 3 days.
Following subcutaneous injection:
Meat and offal: 12 days.
Milk: 4 days.

Sheep:
Meat and offal: 4 days.
Milk: 3 days.

Goats:
Meat and offal: 6 days.
Milk: 4 days.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antibacterials for systemic use, fluoroquinolones.
ATC-vet code: **QJ01MA90.**

5.1. Pharmacodynamics properties

Mode of action
Two enzymes essential for 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 cleavage and closure reactions. Initially, the two strands of the double helix are separated. Then, a distant segment of DNA passes into this gap before the strands close. Target inhibition is caused by noncovalent binding of fluoroquinolone molecules to an intermediate state in this sequence of reactions, in which the DNA is cleaved but both strands are covalently retained by the enzymes. Replication forks and translation complexes cannot pass beyond these enzyme—DNA—fluoroquinolone complexes, and inhibition of DNA and mRNA synthesis triggers rapid and concentration-dependent death of pathogenic bacteria.

Antibacterial spectrum
Enrofloxacin is active against many Gram-negative bacteria, Gram-positive bacteria and Mycoplasma spp.
In vitro susceptibility has been demonstrated against strains of (i) Gram-negative species, such as Pasteurella multocida and Avibacterium (Haemophilus) paragallinarum and (ii) Mycoplasma gallisepticum and Mycopisma synoviae (see section "Special precautions for use").

Types and mechanisms of resistance
Resistance to fluoroquinolones has been reported to have five sources: (i) point mutations in genes coding for DNA gyrase and/or topoisomerase IV, leading to changes in the respective enzymes; (ii) changes in drug permeability in Gram-negative bacteria; (iii) efflux mechanisms; (iv) plasmid-borne resistance; and (v) gyrase protection proteins. All mechanisms lead to decreased susceptibility of bacteria to fluoroquinolones. Cross-resistance within the fluoroquinolone class of antimicrobials is common.

5.2 Pharmacokinetic information

Enrofloxacin is rapidly absorbed after parenteral injection. Bioavailability is high (approximately 100% in cattle) with a low to moderate plasma protein binding (approximately 20 to 50%).
Enrofloxacin and ciprofloxacin distribute well into all target tissues, e.g. lung, kidney, skin and liver, reaching 2- to 3-fold higher concentrations than in plasma. Parent substance and active metabolite are cleared from the body via urine and faeces.
Accumulation in plasma does not occur following a treatment interval of 24 h.
In milk, most of drug activity consists on ciprofloxacin. Overall drug concentrations peak at 2 hours after treatment showing an approximately 3-fold higher total exposure over the 24 hours dosing interval compared to plasma.

	Cattle	Cattle
Dose rate (mg/kg bw)	5	5
Route of administration	iv	sc
Tmax (h)	/	3.5
Cmax (µg/ml)	/	0.733
AUC (µg·h/ml)	9.8	5.9
Terminal half-life (h)	/	7.8
Elimination half-life (h)	2.3	
F (%)	/	88.2

6. PHARMACEUTICAL INFORMATION

6.1 List of Excipients:

n-Butyl alcohol
Potassium hydroxide
Purified water

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: 2 years.
Shelf life after first opening the container: use within 28 days, do not store.

6.4. Special precautions for storage

Store below 25°C.
Protect from light and moisture.
Keep out of the reach of children.
To be used as directed by the registered veterinary practitioner only.

6.5. Nature and composition of primary conditioning

Cardboard box with glass vial injection.
Vial is closed with a bromobutyl rubber stopper and sealed with an aluminum flip off seal.
Pack sizes: 10ml Vial, 50ml Vial & 100ml Vial

SPECIAL PRECAUTIONS FOR THE DISPOSAL OF WASTE MATERIALS
UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS

Waste materials derived from the use of such products
Medicinal products should not be disposed of via wastewater or household waste.
Use return systems for unused veterinary medicinal products or waste materials derived from such products, in accordance with local requirements and national collection systems applicable to the veterinary medicinal product concerned.

Treated animals should be kept in shelters throughout the treatment period and their droppings should be collected and NOT used for soil fertilization.

7. MARKETING AUTHORISATION HOLDER

Nawan Laboratories (Pvt.) Ltd.
Plots No. 136-138, Sector-15,
Korangi Industrial Area, Karachi-74900, Pakistan.

8. MARKETING AUTHORISATION NUMBER

Reg. No.: 020803

9. DATE OF FIRST AUTHORISATION

Date of Reg: 20-01-1998

10. DATE OF REVISION OF THE TEXT

17-02-2025

MANUFACTURED BY:

NAWAN LABORATORIES (PVT) LTD. | 136, Sector 15, Korangi Industrial Area, Karachi-74900, Pakistan.