Encure-10 Injection
(Enrofloxacin)

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Encure-10 Injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Constituents mg per ml
Enrofloxacin 100mg

Relevant Constituents of the Excipients
Benzyl alcohol 20mg
n-butyl alcohol 30mg

For full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Solution for injection.
Clear pale yellow injectable 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.

Indicated for the treatment of local signs (inflammation, milk quality and yield) associated with peracute/acute mastitis in lactating dairy cattle caused by E. coli, where herd history and previous sensitivity testing indicate enrofloxacin as the drug of choice.

4.3 Contraindications

Enrofloxacin injection should not be used for prophylaxis

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

i. Special precautions for use in animals

Normal sterile precautions should be taken.

The safety of the product has not been established in calves when administered by the intravenous route and use of this route of administration in calves is therefore not recommended.

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.

ii. Special precautions to be taken by the person administering the medicinal product to animals

Enrofloxacin injection 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.

iii. Other precautions

None.

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 Amount(s) to be administered and administration route

To ensure correct dosage, body weight should be determined as accurately as possible to avoid underdosing.

Dosage and duration of treatment

For respiratory infections in cattle: administer by subcutaneous injection.

- A single dose of 7.5 mg/kg bodyweight (7.5 ml per 100 kg bodyweight)

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

For *E. coli* mastitis in cattle: administer by slow intravenous injection.

- 5.0 ml per 100 kg bodyweight (5 mg enrofloxacin per kg bodyweight) daily for 2 days.

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

A dose of 25 mg/kg bodyweight administered by the subcutaneous route 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)

Subcutaneous Use:
Meat and offal: 14 days. Milk: 84 hours.

Intravenous Use:
Meat and offal: 4 days. Milk: 72 hours.

5. PHARMACOLOGICAL 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.

Molecular resistance to fluoroquinolones has been observed to arise from two principal sources, (i) alteration to DNA gyrase or topoisomerase IV and (ii) alterations in drug permeability of the bacterial cell. Both mechanisms lead to a reduced susceptibility of the bacteria to fluoroquinolones. Clinical resistance is dependent on several mutations accumulating in a step-wise manner.

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 µg/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.

After an intravenous dose of 5 mg enrofloxacin per kg body weight (bw) to lactating dairy cattle, the total systemic exposure over the dosing interval of
24 h was at 7.1 mg*h/L. In cattle serum, approximately 30% of drug exposure (2.31 mg*h/L) consisted of ciprofloxacin, the active metabolite of enrofloxacin. The drug was well distributed into the body compartments (V_{enro} = 1.5 L/kg, V_{cipro} = 8.51 L/kg). Total body clearance was 0.71 L/h/kg. In milk, most of drug activity consisted of ciprofloxacin. Overall drug concentrations peaked at 4.1 mg/kg two hours after treatment. Overall drug exposure over 24 h was 22.1 mg*h/L. The actives were eliminated from milk with a mean exposure half-life of 2.8 h.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Benzyl alcohol
Arginine
n-butyl alcohol
Water for injection

6.2 Incompatibilities

None known.

6.3 Shelf-life

Shelf-life of the product as packaged for sale: 2 years
Shelf-life after first opening the container: 28 days

6.4 Special precautions for storage

Do not store above 25°C.
Following withdrawal of the first dose, use the product within 28 days. Do not freeze.
Discard if visibly contaminated.

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: 100ml

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products, if appropriate

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

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:

Date of Reg.: 20-01-1998

10. DATE OF REVISION OF THE TEXT Date:

25-07-2024

MANUFACTURED BY:

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