INJECTION
ENCURE-10
(Enrofloxacin)
انکیور-۱۰ انجکشن

Encure-20%
(Enrofloxacin) Injection
انکیور-۲۰ فیصد انجکشن

Encure-20 Oral Solution
(ENROFLOXACIN)
انکیور-۲۰ اورل سلوشن

ORAL SOLUTION
ENROCIN
[ENROFLOXACIN]
انروسین اورل سلوشن

1 QUALITATIVE AND QUANTITATIVE COMPOSITION

1. **Encure-10 Injection**
   Each ml contains: Enrofloxacin…100mg
   (BP Specification)

2. **Encure-20% Injection**
   Each ml contains: Enrofloxacin…200mg
   (BP Specification)

3. **Encure-20 Oral Solution**
   Each ml contains: Enrofloxacin…200mg
   (BP Specification)

4. **Enrocin Oral Solution**
   Each ml solution contains: Enrofloxacin ... 100 mg.
   (BP Specification)

2 CLINICAL PARTICULARS

2.1 Target Species

Cattle, buffalo, Sheep, Goat & Poultry

2.2 Indications for use, specifying the target species

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.

2.3 Contraindications

Do not use in cases of resistance against other fluoroquinolones, due to the potential for cross-resistance. Do not use for prophylaxis.

Do not use in case of hypersensitivity to the active substance or to any of the excipients.

Do not use in growing horses because of possible deleterious damage on articular cartilage.

2.4 Special warnings for each target species

None known.

2.5 Special precautions for use

Special precautions for use in animals

The safety of the product has not been established in pigs or calves when administered by the Intramuscular route and use of this route of administration is not recommended in these animal groups.

Degenerative changes of articular cartilage were observed in calves treated orally with 30 mg enrofloxacin/kg bw 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 with clinical signs.

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

This product is an alkaline solution. Wash any splashes from skin and eyes immediately with water. People with known hypersensitivity to (fluoro)quinolones should avoid contact with this product. Do not eat, drink or smoke whilst using the product.

In case of accidental self-injection seek medical advice immediately and show the package leaflet or label to the physician.

2.6 Adverse reactions (frequency and seriousness)

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

2.7 Use during pregnancy, lactation or lay

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

2.8 Interaction with other medicinal products and other forms of interactions

None known.

2.9 Amounts to be administered and administration route

Intramuscular or subcutaneous use.

Repeated injections should be made at different injection sites.

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

For Encure-10 injection / Encure-20 Oral Solution / Enrocin Oral Solution

Cattle, Buffalo & Poultry:

5 mg of enrofloxacin/kg bw, corresponding to 1 ml/20 to 40 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 to 40 kg bw, once daily for 5 days.

The product can be administered by slow Intramuscular or subcutaneous administration.

Acute mastitis caused by Escherichia coli: 5 mg enrofloxacin/kg bw, corresponding to 1 ml/20 to 40 kg bw, by slow Intramuscular injection or Orally in case of oral solution 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 one subcutaneous injection site.

For Encure-20% injection

Cattle, Buffalo, Sheep & Goat:

5 mg of enrofloxacin/kg bw, corresponding to 1 ml/40 to 80 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/40 to 80 kg bw, once daily for 5 days.

The product can be administered by subcutaneous administration.

Acute mastitis caused by Escherichia coli: 5 mg enrofloxacin/kg bw, corresponding to 1 ml/40 to 80 kg bw, by slow Intramuscular 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 one subcutaneous injection site.

2.10 Overdose (symptoms, emergency procedures, antidotes), if necessary
Do not exceed the recommended dose. In accidental overdose there is no antidote and treatment should be symptomatic.

No target animal studies were performed in cattle. In pigs, no adverse effects were observed after administration of the product at 5 times the recommended therapeutic dose.

2.11 Withdrawal period(s)
For Encure-10 Injection
Cattle & Buffalo:
Following Intramuscular injection:
Meat and offal: 5 days.
Milk: 3 days.

Following subcutaneous injection:
Meat and offal: 12 days.
Milk: 4 days.

For Encure-20% Injection
Cattle & Buffalo, sheep & Goat:

Following subcutaneous injection:
Meat and offal: 28 days.
Milk: 7 days.

For Encure-20 Oral Solution
Poultry
Following oral administration:
Meat 7 days.

For Enrocin Oral Solution
Poultry
Following oral administration:
Meat 7 days.

3 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES
Pharmacotherapeutic group: Anti-infectives for systemic use: fluoroquinolones ATCvet code: QJ01MA90

3.1 Pharmacodynamic properties
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. Target inhibition is caused by non-covalent binding of fluoroquinolone molecules to these 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. The mode of action of enrofloxacin is bactericidal and bactericidal activity is concentration dependent.

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.

3.2 Pharmacokinetic particulars
The pharmacokinetics of enrofloxacin in dogs and cats are such that oral and parenteral administration leads to similar serum levels. Enrofloxacin 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 an Intramuscular 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 (Venro= 1.5 L/kg, Vcipro= 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.

4 PHARMACEUTICAL PARTICULARS

4.1 Major incompatibilities
None known.

4.2 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

4.4 Special precautions for storage
Do not store above 25°C & Do not freeze.
Keep the vial in the outer carton in order to protect from light. Discard unused material. Keep out of reach of children.

How to Supplied:
Encure-10 Injection
100ml Vial, 50ml, 10ml Vial and 10x10ml Vials

Encure-20% Injection
100ml Vial, 10ml Vial

Encure-20 Oral Solution
1 Liter Bottle.

Enrocin Oral Solution
30ml, 100ml & 1 Liter Bottle

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