CEFUR-RTU

INJECTION

(Ceftiofur Hydrochloride)

سیفر۔ آر ٹی یو انجکشن

۱۰ ملی لیٹر، ۵۰ ملی لیٹر اور ۱۰۰ ملی لیٹر

10ml, 50ml & 100ml Injection

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

CEFUR RTU 50 mg/ml suspension for injection for cattle

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:
Active substance:
Ceftiofur (as ceftiofur hydrochloride) 50.0 mg

3. CLINICAL INFORMATION

3.1 Target species

Cattle, sheep and goat

3.2 Indications for use for each the target species

Infections associated with bacteria sensitive to ceftiofur:

Cattle:

For the treatment of bacterial respiratory disease associated with Mannheimia haemolytica, Pasteurella multocida and Histophilus somni.
For the treatment of acute interdigital necrobacillosis (panaritium, foot rot), associated with Fusobacterium necrophorum and Prevotella melaninogenica (Porphyromonas asaccharolytica).
For treatment of the bacterial component of acute post-partum (puerperal) metritis within 10 days after calving associated with Escherichia coli, Trueperella pyogenes and Fusobacterium necrophorum, sensitive to ceftiofur. The indication is restricted to cases where treatment with another antimicrobial has failed.

3.3 Contraindications

Do not use in cases of hypersensitivity to ceftiofur and other β-lactam antibiotics or to any of the excipients.
Do not use in cases of known resistance to ceftiofur or other beta-lactam antibiotics. Do not inject intravenously.

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in target species:

This product does not contain an antimicrobial preservative.
The product selects for resistant strains such as bacteria carrying extended spectrum betalactamases (ESBL) and may constitute a risk to human health if these strains disseminate to humans e.g. via food. For this reason, the product should be reserved for the treatment of clinical conditions which have responded poorly, or are expected to respond poorly (refers to very acute cases when treatment must be initiated without bacteriological diagnosis) to first line treatment. Official, national and regional antimicrobial policies should be taken into account when the product is used. Increased use, including use of the product deviating from the instructions given in the SPC, may increase the prevalence of such resistance.
Whenever possible, the product should only be used based on susceptibility testing.
The product is intended for treatment of individual animals. Do not use for disease prevention or as a part of heard health programmes. Treatment of groups of animals should be strictly restricted to ongoing disease outbreaks according to the approved conditions of use.
Do not use as prophylaxis in case of retained placenta.
Shake vigorously before use for 1 minute or until the complete resuspension of the product.

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

Penicillin and cephalosporins may cause hypersensitivity (allergy) following injection, inhalation, ingestion or skin contact. Hypersensitivity to penicillin may lead to cross-reactions to cephalosporins and vice versa. Allergic reactions to these substances may occasionally be serious. Do not handle this veterinary medicinal product if you know you are sensitized, or if you have been advised not to work with such preparations.
Handle this product with great care to avoid exposure taking all recommended precautions.
In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.
If you develop symptoms following exposure such as skin rash, you should seek medical advice and show the doctor this warning. Swelling of the face, lips or eyes or difficulty in breathing are more serious symptoms and require urgent medical attention.
Wash hands after use.

Special precautions for the protection of the environment: Not applicable.

3.6 Adverse events

P cattle:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Hypersensitivity reaction[1] Allergic reaction (e.g. skin reactions, anaphylaxis)[2]

[1] Unrelated to dose.
[2] In this case, the treatment should be withdrawn.

Cattle:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Injection site reaction (e.g. as tissue discoloration[1])[2]

[1] Subcutaneous tissue and/or fascial surface of the muscle.
[2] Mild inflammatory reactions, clinical resolution is reached in most animals by 10 days after injection although slight tissue discoloration may persist for 28 days or more.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See also section 16 of the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

The safety of the veterinary medicinal product has not been established during pregnancy or lactation. Use only according to the benefit/risk assessment by the responsible veterinarian.
Laboratory studies have not produced any evidence of a teratogenic, foetotoxic or maternotoxic effects.

3.8 Interaction with other medicinal products and other forms of interaction

The bactericidal properties of cephalosporins are antagonized by simultaneous use of bacteriostatic antibiotics (macrolides, sulfonamides and tetracyclines). Aminoglycosides may have a potentiating effect on cephalosporins.

3.9 Administration routes and dosage

Intramuscular or subcutaneous use.

To ensure a correct dosage, body weight should be determined as accurately as possible. The use of suitably calibrated measuring equipment is recommended.

Cattle:

Respiratory disease: 1 mg ceftiofur /kg bw/day for 3 to 5 days by subcutaneous injection, i.e. 1 ml/50 kg bw at each injection.
Acute inter digital necrobacillosis: 1 mg/kg bw/day for 3 days by subcutaneous injection, i.e. 1 ml/50 kg bw at each injection.
Acute post-partum metritis within 10 days after calving: 1 mg/kg bw/day for 5 consecutive days by subcutaneous injection, i.e. 1 ml/50 kg bw at each injection.
In case of acute post-partum metritis, additional supportive therapy might be required in some cases.

Not more than 7 ml should be administered at any one intramuscular injection site in cattle. Subsequent injections must be given at different sites. Shake vigorously before use for 1 minute or until the complete resuspension of the product.
The user should select the most appropriate vial size.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

In cattle, no signs of systemic toxicity have been observed following substantial parenteral overdosages.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

3.12 Withdrawal period(s)

Cattle:

Meat and offal: 6 days. Milk: zero hours.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

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

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.

5.3. Special precautions for storage

This veterinary medicinal product does not require any special storage conditions.

- Store below 30°C in a dry place.
- Protect from light. Do not freeze.
- Keep out of reach of children

5.4 How Supplied :

50ml & 100ml Vial Protector
10ml Unit Carton

5.5 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater <or household waste>.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

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