CEMAY 50MG/ML

Ceftiofur 50 mg

DATA SHEET

INDICATIONS

Licensed for the treatment of Infections associated with bacteria sensitive to ceftiofur:

In pigs:

- For the treatment of bacterial respiratory disease associated with Pasteurella multocida, Actinobacillus pleuropneumoniae and Streptococcus suis.

In cattle:

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

LIST No	UNIT PACKAGE	OUTER SIZE
1CEM001	100ml	40

See reverse for Administration & Dosage

BENEFITS

- Powerful third generation cephalosporin
- Zero milk withdrawal
- Short meat withdrawal
- Broad spectrum action

Cemay 50 mg/ml


Ceftiofur 50 mg - Suspension for injection for pigs and cattle

PRESENTATION
A white or slightly yellow coloured opaque suspension for injection containing Ceftiofur 50mg/ml (as ceftiofur hydrochloride).

USES
Metritis, Respiratory Disease, Lameness

DOSAGE AND ADMINISTRATION
Pigs:
3 mg ceftiofur /kg bw/day for 3 days via intramuscular route, i.e. 1 ml/16 kg bw at each injection.

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 interdigital 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.

- A maximum volume of 6 ml may be administered in each injection site.
- Subsequent injections must be given at different sites.
- To ensure a correct dosage body weight should be determined as accurately as possible to avoid under dosing.
- As the vial cannot be broached more than 40 times, the user should choose the more appropriate vial size.

CONTRA-INDICATIONS & WARNINGS
- **Do not** administer to an animal previously found to be hypersensitive to ceftiofur and other β-lactam antibiotics or to any of the excipients.
- **Do not** inject intravenously.

The product should not be used in cases of known resistance to ceftiofur or other beta-lactam antibiotics.
- **Do not** use in poultry (including eggs) due to risk of spread of antimicrobial resistance to humans.

SPECIAL WARNINGS FOR EACH TARGET SPECIES
None known.

WITHDRAWAL PERIODS
Pigs:
- Meat and offal: 5 days.

Cattle:
- Meat and offal: 8 days
- Milk: zero days

PHARMACEUTICAL INFORMATION & PRECAUTIONS
Pharmacotherapeutic group:
Antibacterials for systemic use.
Third generation Cephalosporins.
ATC Vet Code: QJ01DD90.

PHARMACODYNAMIC PROPERTIES
- Ceftiofur is a third generation of cephalosporin, which is active against many Gram-positive and Gram-negative bacteria, including β-lactamase producing strains.
- Beta-lactams act by interfering with synthesis of the bacterial cell wall. Cell wall synthesis is dependent on enzymes that are called penicillin-binding proteins (PBP's).
- Ceftiofur is active against the following microorganisms which are involved in respiratory diseases in pigs:

Pasteurella multocida, Actinobacillus pleuropneumoniae and Streptococcus suis. Bordetella bronchiseptica is intrinsically non-susceptible to ceftiofur.
- It is also active against bacteria involved in respiratory disease in cattle: Pasteurella multocida, Mannheimia haemolytica, Haemophilus somnus; bacteria involved in acute bovine foot rot (interdigital necrobacillosis) in cattle: Fusobacterium necrophorum, Bacteroides melaninogenicus (Porphyromonas asaccharolytica); and bacteria associated with acute post-partum (puerperal) metritis in cattle: Escherichia coli, Arcanobacterium pyogenes and Fusobacterium necrophorum.

PHARMACOKINETIC PARTICULARS
- After administration, ceftiofur is quickly metabolised to desfuroylceftiofur, the principal active metabolite.
- Desfuroylceftiofur has an equivalent anti-microbial activity to ceftiofur against the bacteria involved in respiratory disease in animals. The active metabolite is reversibly bound to plasma proteins. Due to transportation with these proteins, the metabolite concentrates at a site of infection, is active and remains active in the presence of necrotic tissue and debris.

PHARMACEUTICAL PARTICULARS
LIST OF EXCIPIENTS:
- Hydrogenated soya lecithin
- Sorbitan oleate
- Cotton seed oil

SPECIAL PRECAUTIONS FOR USE
SPECIAL PRECAUTIONS FOR USE IN ANIMALS
- Shake the bottle well for 30 seconds before use to bring the veterinary medicinal product back into suspension.
- In case of the occurrence of allergic reaction the treatment should be withdrawn.
- Cemay 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, Cemay 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, Cemay should only be used based on susceptibility testing.
- Cemay is intended for treatment of individual animals. Do not use for disease prevention or as a part of herd health programmes. Treatment of groups of animals should be strictly restricted to on-going disease outbreaks according to the approved conditions of use.
- **Do not** use as prophylaxis in case of retained placenta.

SPECIAL PRECAUTIONS TO BE TAKEN BY THE PERSON ADMINISTERING THE MEDICINAL PRODUCT TO ANIMALS
- Penicillins and cephalosporins may cause hypersensitivity (allergy) following injection, inhalation, ingestion or skin contact. Hypersensitivity to penicillins may lead to cross reactions to cephalosporins and vice versa. Allergic reactions to these substances may occasionally be serious.
- Do not handle this product if you know you are sensitised, or if you have been advised not to work with such preparations.
- If you develop symptoms following exposure such as a skin rash, you should seek medical advice and show the doctor this warning.
- Swelling of the face, lips or eyes or difficulty with breathing are more serious symptoms and require urgent medical attention.
- Handle this product with great care to avoid exposure.

Wash hands after use.

ADVERSE REACTIONS (FREQUENCY & SERIOUSNESS)
- Hypersensitivity reactions unrelated to dose can occur. Allergic reactions (e.g. skin reactions, anaphylaxia) may occasionally occur. In case of the occurrence of allergic reaction the treatment should be withdrawn.
- In pigs, mild reactions at the injection site, such residual lesions in the inter-muscular connective tissue consisting of round clear areas, have been observed in some animals for up to 20-22 days after injection.
- In cattle, mild inflammatory reactions at the injection site, such as tissue oedema and discoloration of the subcutaneous tissue and/or fascia I surface of the muscle may be observed. Clinical resolution is reached in most animals by 10 days after injection, although slight tissue discoloration may persist for 32 days or more.

USE DURING PREGNANCY, LACTION OR LAY
- Studies in laboratory species have not produced any evidence of teratogenic, foetotoxic or maternotoxic effects. Safety has not been established in the target species during pregnancy or lactation. Use only accordingly to the benefit/ risk assessment by the responsible veterinarian.

INTERACTION WITH OTHER MEDICINAL PRODUCTS AND OTHER FORMS OF INTERACTION
- The bactericidal properties of cephalosporins are antagonized by simultaneous use of bacteriostatic antibiotics (macrolides, sulphonamides and tetracyclines).

OVERDOSE (SYMPTOMS, EMERGENCY PROCEDURES, ANTIDOTES)
- The low toxicity of ceftiofur has been demonstrated in pigs using ceftiofur sodium at doses in excess of 8 times the recommended daily dose of ceftiofur intramuscularly administered for 15 consecutive days.
- In cattle, no signs of systemic toxicity have been observed following substantial parenteral over-dosages

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

NATURE AND COMPOSITION OF IMMEDIATE PACKAGING
Cardboard boxes with one 100 ml or one 250 ml plastic bottle of polypropylene with closures of bromobutyl rubber and aluminium cap.
Not all pack sizes may be marketed.

SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED VETERINARY MEDICINAL PRODUCT OR WASTE MATERIALS 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
POM-V

MARKETING AUTHORISATION NUMBER
VM 42204/ 4000

DISTRIBUTED IN THE UK BY
Bimeda UK
Unit 2, Bryn Cefni Industrial Park
Llangefni, Anglesey,
Wales, LL777XA
Tel: +44 (0) 1248 725 400

Use Medicines Responsibly.
Advice should be sought from prescriber before use.
www.noah.co.uk

TAKE TIME  OBSERVE LABEL DIRECTIONS

www.bimeda.co.uk