

TECHNICAL NOTES



Ceftiofur Sodium Lyophilised Powder for Injection



Active Constituent

Each powder vial contains: 4 g ceftiofur (as ceftiofur sodium)

The 4 g vial is reconstituted by adding 80 mL water for injection.

Each mL of reconstituted solution contains: 50 mg ceftiofur (as ceftiofur sodium)

Indications

elevel+ Ceftiofur Sodium Lyophilised Powder for Injection is indicated for the treatment of:

- Equine respiratory diseases, caused by *Streptococcus equi* and *Streptococcus zooepidemicus* organisms susceptible to ceftiofur.
- Bovine respiratory diseases caused by *Mannheimia haemolytica*, *Pasteurella multocida* and *Haemophilus somnus*.
- Canine urinary tract infections caused by ceftiofur sensitive pathogens.

Indiscriminate use of elevel+ Ceftiofur Sodium Lyophilised Powder for Injection could contribute to the development of antibiotic resistance.

Restraints

DO NOT USE for mass medication – for individual animal treatment only.

DO NOT USE by the intramammary, topical or oral route in food producing animals.

DO NOT USE for the treatment of mastitis in dairy cattle.

Contraindications

elevel+ Ceftiofur Sodium Lyophilised Powder for Injection is contraindicated for use in animals previously found to be hypersensitive to the drug.

Precautions

Antimicrobial drugs, including penicillins and cephalosporins, can cause allergic reactions in sensitised individuals. To minimize the possibility of such a reaction, users of such antimicrobial products, including elevel+ Ceftiofur Sodium Lyophilised Powder for Injection, should avoid direct contact of the product with the skin and mucous membranes.

Not recommended for use other than by subcutaneous injection in dogs.

Side Effects

The use of elevel+ Ceftiofur Sodium Lyophilised Powder for Injection may result in some signs of immediate and transient local pain at the injection site.

The administration of ceftiofur to horses under conditions of stress may be associated with acute diarrhoea that could be fatal. If acute diarrhoea is observed, discontinue use of this drug and initiate appropriate therapy.

Dosage & Administration

The lyophilised powder must be reconstituted with Water for Injections before use.

For ease in reconstitution, use an 18-gauge needle or larger.

Reconstituted elevet+ Ceftiofur Sodium Lyophilised Powder for Injection should be administered by intramuscular injection (horses and cattle) or subcutaneous injection (dogs) at the following rates:

Horses (intramuscular): The daily dose rate for horses is 2 mg ceftiofur per kilogram of bodyweight (4 mL per 100 kg body weight). Treatments should be repeated every 24 hours for 4 to 5 treatments and should be continued for 48 hours after symptoms have disappeared. If no response is observed within 4-5 days, the diagnosis should be reevaluated.

Cattle (intramuscular): The daily dose rate for cattle is 1 mg ceftiofur per kilogram of body weight (2 mL per 100 kg body weight). Treatments should be repeated every 24 hours and continued for 48 hours after symptoms have disappeared. If no response is observed within 3 days, the diagnosis should be re-evaluated.

Dogs (subcutaneous): The daily dose rate for dogs is 2 mg ceftiofur per kilogram of bodyweight (0.2 mL per 5 kg body weight). Treatments should be repeated every 24 hours for a course of 5 to 14 treatments, subject to clinical response. If no improvement is seen within 3-5 days, the diagnosis should be re-evaluated.

General Directions

elevet+ Ceftiofur Sodium Lyophilised Powder for Injection contains the sodium salt of ceftiofur, which is a broad-spectrum cephalosporin antibiotic active. Like other cephalosporins, ceftiofur exerts its bactericidal effect through the inhibition of cell wall synthesis.

The colour of the product may vary from off-white to a tan colour. These colour differences do not affect the potency of the product.

Withholding Periods

MEAT (Cattle): DO NOT USE less than 1 day before slaughter for human consumption.

MEAT (horses): DO NOT USE less than 28 days before slaughter for human consumption.

MILK (Cattle): Zero (0) days Any variation by the prescribing veterinarian to the approved use pattern, may require an extended withholding period.

Trade Advice

EXPORT SLAUGHTER INTERVAL (ESI): An ESI has not been established for this product.

Note - observing the meat withholding period may not be sufficient to mitigate potential risks to export trade. Trade advice should be sought from Avet Health Ltd on 1800 28 38 28 before using this product.

Safety Data Sheet

For Safety Data Sheet see www.avet.health

First Aid

If poisoning occurs, contact a doctor or Poison Information Centre. Phone Australia 13 11 26.

Disposal

Dispose of container by wrapping with paper and putting in garbage.

Discarded needles/sharps should immediately be placed in a designated and appropriately labelled 'sharps' container.

Storage

Lyophilised powder vial: Store below 25 °C (Air Conditioning). Protect from light.

Reconstituted product in vial: Use reconstituted product within 12 hours if stored below 25°C (air conditioning), within 7 days when stored between 2°C and 8°C (refrigerate) or within 4 weeks when stored below -5°C (freeze). When frozen, some breakages of vials may occur. Thaw by immersing the vial in hot, running tap water until a clear, ice-free solution is obtained and then use according to label. Do not freeze and thaw reconstituted product more than once. Discard the unused portion.

Presentation

1x powder vial containing 4g of ceftiofur (as ceftiofur sodium)

1x vial containing 80ml water for injection

Poisons schedule

S4

Registration Numbers

APVMA Approval Number: 94230