EFICUR

50 mg/ml ceftiofur suspension for injection for swine and cattle

COMPOSITION PER ML:
Ceftiofur (as hydrochloride) 50 mg
Oil based vehicle q.s. ad. 1 ml

PHARMACODYNAMICS AND PHARMACOKINETICS PROPERTIES:

Ceftiofur is a late generation cephalosporin, which is active against Gram-positive and Gram-negative bacteria. Like all beta-lactam antibiotics, ceftiofur inhibits bacterial cell wall synthesis, thereby exerting bactericidal properties.
Cell wall synthesis is dependent on enzymes that are called penicillin-binding proteins (PBP´s). Bacteria may develop resistance to cephalosporins by 1) having penicillin binding proteins insensitive to an otherwise effective β-lactam; 2) altering cell permeability to β--lactams; 3) producing β-lactamases that cleave the β--lactam ring of the antibiotic, or 4) active efflux.
Some β--lactamases, documented in Gram-negative enteric organisms, may lead to varying degrees of cross resistance between cephalosporins, as well as with penicillins, ampicillins and β-lactam inhibitor combinations.
Ceftiofur is active against the following microorganisms which are involved in respiratory diseases in swine: *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): *Fusobacterium necrophorum, Bacteroides melaninogenicus* (*Porphyromonas asaccharolyitica*); and bacteria associated with acute post-partum (puerperal) metritis in cattle: *Escherichia coli, Arcanobacterium pyogenes* and *Fusobacterium necrophorum*.
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. It is reversibly bound to plasma proteins and as a result, the metabolite concentrates at sites of infection. It remains active in the presence of necrotic tissue and debris.
Pigs: A single intramuscular dose of the product at 3 mg ceftiofur/kg body weight resulted in mean C_{max} of approximately 9 µg/mL after about 1 hour. The terminal elimination half-life ($t_{1/2}$) of desfuroylceftiofur was about 23 hours. No accumulation of desfuroylceftiofur has been observed after a dose of 3 mg ceftiofur/kg bw/day administered daily over 3 days. Elimination occurs mainly via the urine (more than 70%); 12-15 % is eliminated via faeces. Ceftiofur is completely bioavailable following intramuscular administration.
Cattle: A single subcutaneous dose of the product at 1 mg ceftiofur/kg resulted in mean C_{max} of approximately 2 µg/mL after about 2.5 hours. After administration of the product, the terminal elimination half-life ($t_{1/2}$) of desfuroylceftiofur in cattle is approximately 18 hours. In other studies in healthy cows, a mean C_{max} of approximately 2.25 µg/mL was reached in the endometrium about 5 hours after a single administration of cefiofur. Maximum mean concentrations reached in caruncles and lochiae of healthy cows were about 1.
No accumulation of desfuroylceftiofur has been observed after a daily treatment of ceftiofur over 5 days. Elimination occurs mainly via the urine (more than 55%). 31% is eliminated in the faeces.
Ceftiofur is completely bioavailable following subcutaneous administration.

INDICATIONS:
Infections associated with bacteria sensitive to ceftiofur:
Swine:
- Treatment of bacterial respiratory disease associated with *Pasteurella multocida, Actinobacillus pleuropneumoniae* and *Streptococcus suis*.

Cattle:
- For the treatment of bacterial respiratory disease associated with *Mannheimia haemolytica* (former *Pasteurella haemolytica*), *Pasteurella multocida* and *Haemophilus somnus*.
- For the treatment of acute interdigital necrobacillosis (panaritium, foot rot) associated with *Fusobacterium necrophorum* and *Bacteroides melaninogenicus* (*Phorphyromonas asaccharolytica*).
- For the 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*.

CONTRAINDICATIONS: Do not administer to an animal previously found to be hypersensitive to ceftiofur and other β-lactam antibiotics.
ADVERSE REACTIONS:
In swine, mild reactions at the injection site, such as discoloration of the fascia or fat, have been observed in some animals for up to 20 days after injection.
In cattle, mild inflammatory reactions at the injection site, such as tissue œdema and discoloration of the subcutaneous tissue and/or facial 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 28 days or more.
TARGET SPECIES: Swine and cattle.
DOSAGE AND ROUTE OF ADMINISTRATION:
Swine: 3 mg ceftiofur/kg b.w./day for 3 days by intramuscular injection, i.e. 1 ml of EFICUR/16 kg b.w./day.
Cattle: Treatment of respiratory disease: 1 mg ceftiofur/kg b.w./day for 3 to 5 days by subcutaneous injection, i.e. 1 ml of EFICUR/50 kg b.w./day.
Treatment of acute interdigital necrobacillosis: 1 mg ceftiofur/kg b.w./day for 3 days by subcutaneous injection, i.e. 1 ml of EFICUR/50 kg b.w./day.
Acute post-partum metritis within 10 days after calving: 1 mg ceftiofur/kg b.w./day for 5 consecutive days by subcutaneous injection, i.e. 1 ml of EFICUR/50 kg b.w./day.
Subsequent injections must be given at different sites.
In case of acute post-partum metritis, additional supportive therapy might be required in some cases.
WITHDRAWAL PERIOD: Swine: Meat: 5 days after last treatment. **Cattle:** Meat: 8 days after last treatment. Milk: Zero days.
INTERACTIONS: None known.
USE ON PREGNANCY AND LACTATION: 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. Use only according to the benefit/risk assessment by the responsible veterinarian.
SPECIAL STORAGE PRECAUTIONS: Shake before use. Do not store at temperatures above 25 ºC. Keep medicine out of reach of children. Jauhi Ubat Dari Kanak-kanak. Discard the product within 28 days of opening.
SPECIAL WARNINGS ADVICE ON CORRECT ADMINISTRATION:
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. People with known hypersensitivity to penicillins or cephalosporins should avoid contact with the product. In the case of accidental self-injection or following exposure such as a skin rash, seek medical advice immediately and show the package leaflet or the label to the physician. Swelling of the face, lips or eyes or difficulty with breathing are more serious symptoms and require urgent medical attention.
Dispose waste material by incineration.
DATE OF REVISION OF TEXT:
1st of January 2026
PRESENTATION:
Box with one 100 ml glass bottle.
Box with one 250 ml glass bottle with protector.
Box with one 50 ml PET bottle.
Box with one 100 ml PET bottle.
Box with one 250 ml PET bottle.

Registration holder:
HIPRA MALAYSIA SDN BHD
LOT NO. A-03-03A, LEVEL 3,
PLAZA MONT'KIARA, NO. 2,
JALAN KIARA, MONT'KIARA,
50480 KUALA LUMPUR,
WILAYAH PERSEKUTUAN KUALA LUMPUR

Reg. nº MAL10010011HA
FOR ANIMAL TREATMENT ONLY
Controlled Medicine. Ubat Terkawal.
To be supplied only on veterinary prescription.

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