

KEEP OUT OF REACH OF CHILDREN

FOR ANIMAL TREATMENT ONLY

RESTRICTED VETERINARY MEDICINE

EFICUR

**50 mg/mL ceftiofur suspension for injection
for cattle and pigs**

Composition: Each 1mL contains ceftiofur 50mg
(as ceftiofur hydrochloride)

EFICUR is a white or yellowish oily suspension.

ACTIONS:

Swine:

Ceftiofur hydrochloride has excellent *in vitro* and *in vivo* activity against gram-negative pathogens such as *Actinobacillus (Haemophilus) pleuropneumoniae*, *Salmonella choleraesuis*, *Pasteurella multocida*, and the gram-positive pathogen *Streptococcus suis*, all of which singly or in combination can be associated with swine bacterial respiratory disease (swine-bacterial pneumonia).

Ceftiofur also has excellent *in vitro* activity against other gram-negative pathogens such as *E. coli* and *Salmonella typhimurium* and against gram-positive pathogens such as *Staphylococcus aureus*, *Streptococcus agalactiae*, *Streptococcus dysgalactiae*, *Streptococcus uberis* and *Streptococcus bovis*.

Ceftiofur was effective when tested in a variety of mouse disease models involving *E. coli*, *Staphylococcus aureus*, *Streptococcus agalactiae*, *Pasteurella multocida* and *Salmonella typhimurium*.

Cattle:

Ceftiofur hydrochloride has demonstrated excellent *in vitro* and *in vivo* activity against *Fusobacterium necrophorum* and *Bacteroides melaninogenicus (Porphyromonas asaccharolytica)*, the two major pathogens associated with bovine foot rot.

Ceftiofur hydrochloride has also demonstrated excellent *in vitro* and *in vivo* activity against *Pasteurella haemolytica* and *P. multocida*, two of the major pathogenic bacteria associated with bovine respiratory disease (BRD). This antibiotic has also demonstrated excellent *in vitro* and *in vivo* activity against *Histophilus somni (Haemophilus somnus)*, and *in vitro* activity against *Corynebacterium pyogenes*, two other bacterial pathogens associated with bovine respiratory disease.

In addition, ceftiofur has excellent *in vitro* activity against other gram-negative pathogens such as *E. coli*, *Salmonella choleraesuis*, *Salmonella typhimurium* and *Actinobacillus (Haemophilus) pleuropneumoniae* and against gram-positive pathogens such as *Staphylococcus aureus*, *Streptococcus agalactiae*, *Streptococcus dysgalactiae*, *Streptococcus uberis*, *Streptococcus bovis* and *Streptococcus suis*.

Ceftiofur was effective when tested in a variety of mouse disease models involving *E. coli*, *Staphylococcus aureus*, *Streptococcus agalactiae*, *Pasteurella haemolytica*, *Histophilus somni* and *Salmonella typhimurium*.

INDICATIONS:

Infections associated with bacteria sensitive to ceftiofur:

Swine:

- Treatment of swine bacterial respiratory disease associated with *Pasteurella multocida*, *Actinobacillus (Haemophilus) pleuropneumoniae*, *Salmonella choleraesuis*, and *Streptococcus suis* type 2.

Cattle:

- Treatment of bacterial respiratory disease (BRD) associated with *Pasteurella (Mannheimia) haemolytica*, *Pasteurella multocida* and *Histophilus somni*.
- Treatment of acute interdigital necrobacillosis (foot rot) associated with *Fusobacterium necrophorum* and *Bacteroides melaninogenicus (Porphyromonas asaccharolytica)*.
- Acute metritis (0 - 14 days after calving) associated with bacterial organisms susceptible to ceftiofur.

CONTRAINDICATIONS:

Do not administer to an animal previously found to be hypersensitive to ceftiofur and other β -lactam antibiotics.

Do not inject intravenously.

ADVERSE REACTIONS:

Hypersensitivity reactions unrelated to dose can occur. Allergic reactions (e.g. skin reactions, anaphylaxis) may occasionally occur.

In swine, mild reactions at the injection site, such as discolouration 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 oedema and discolouration of the subcutaneous tissue and / or fascial surface of the muscle may be observed. Clinical resolution is reached in most animals by 10 days after injection although slight tissue discolouration may persist for 28 days or more.

If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinarian.

TARGET SPECIES:

Cattle and Pigs

DOSAGE:Swine:

3mg ceftiofur / kg bw (1mL EFICUR / 16kg bw) daily for 3 days by intramuscular injection

Cattle:

Administer by IM or SC injection in the anterior half of the neck.

Treatment of respiratory disease (BRD) and footrot:

1mg ceftiofur / kg bw (1mL EFICUR per 50kg bw) every 24 hours for 3 days.

Additional treatments should be given on days 4 and 5 for cattle that do not respond after the first 3 treatments.

Acute post-partum metritis :

2.2 mg ceftiofur / kg bw (2.2mL EFICUR per 50kg bw) daily for 5 consecutive days.

Subsequent injections must be given at different sites.

In case of acute post-partum metritis, additional supportive therapy might be required in some cases.

No more than 10mL of Eficur should be injected per injection site.

It is prudent to reserve cephalosporin antibiotics for the treatment of clinical conditions which have responded poorly to, or are expected to respond poorly to, other classes of antimicrobials. Indiscriminate use of antimicrobials could contribute to the development of antibiotic resistance.

ADVICE ON CORRECT ADMINISTRATION:

Shake the bottle well before use to bring the product back into suspension. In the case of 250mL vial, remove the protector before shaking. The coloration of the glass vial may not be uniform making it difficult to determine when the product is in suspension. Following the shaking the absence of sediment can be confirmed most readily by inverting the vial and viewing the contents through the base of the vial.

If allergic reaction occurs, the treatment should be withdrawn.

Inappropriate use of the product may increase the prevalence of bacterial resistant to cephalosporins.

Use of the product should be based on susceptibility testing and take into account official and local antimicrobial policies.

Should any apparent growth or discoloration occur, the product should be discarded.

WITHHOLDING PERIODS:

It is an offence for users of this product to cause residues exceeding the relevant MRL in the New Zealand (Maximum Residue Limits of Agricultural Compounds) Food Standards.

Swine:	Meat:	2 days
Cattle:	Meat:	2 days
	Milk:	Nil
	Not for use in bobby calves	

STORAGE:

Keep out of the reach and site of children.

Store at or below 25°C. Do not refrigerate or freeze. Protect from light.

Do not use EFICUR after the expiry date stated on the label.

Shelf-life after first opening the container: 28 days.

SPECIAL WARNINGS:

User Warnings:

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, if you develop symptoms 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.

Special Precautions for Use in Animals:

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 veterinarian.

If you notice any serious effects or other effects not mention in this leaflet, please inform your veterinarian.

DISPOSAL:

Any unused product or waste material should be disposed of in accordance with national requirements.

PACK SIZES:

Box with 1 bottle of 50mL

Box with 1 bottle of 250mL

Pack with 12 bottles of 100mL

Box with 1 bottle of 100mL

Pack with 10 bottles of 100mL

Not all pack sizes may be marketed

Restricted Veterinary Medicine.

Registered pursuant to the ACVM Act, 1997, No A10691. See
www.foodsafety.govt.nz for registration conditions.

Laboratorios Hipra, S.A. Avda. La Selva, 135. 17170 Amer (Girona) Spain
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hipra@hipra.com

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EFICUR

50 mg/mL ceftiofur suspension for cattle and pigs

Suspension for Injection

50mL

Composition per mL: Ceftiofur (as hydrochloride) 50mg in an oily base

TARGET SPECIES

Cattle and Pigs

ADMINISTRATION ROUTE

Swine: intramuscular

Cattle: subcutaneous (or intramuscular)

Read the package leaflet before use

WITHDRAWAL PERIOD

Swine: Meat: 2 days

Cattle: Meat: 2 days

Milk: Nil

Not for use in bobby calves

Store at or below 25°C. Do not refrigerate or freeze. Protect from light.
Any unused product or waste material should be disposed of in accordance
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EFICUR

50 mg/mL ceftiofur suspension for cattle and pigs

Suspension for Injection

100mL

Composition per mL: Ceftiofur (as hydrochloride) 50mg in an oily base

TARGET SPECIES

Cattle and Pigs

ADMINISTRATION ROUTE

Swine: intramuscular

Cattle: subcutaneous (or intramuscular)

Read the package leaflet before use

WITHDRAWAL PERIOD

Swine: Meat: 2 days

Cattle: Meat: 2 days

 Milk: Nil

 Not for use in bobby calves

Store at or below 25°C. Do not refrigerate or freeze. Protect from light.
Any unused product or waste material should be disposed of in accordance
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EFICUR

50 mg/mL ceftiofur suspension for cattle and pigs

Suspension for Injection

250mL

Composition per mL: Ceftiofur (as hydrochloride) 50mg in an oily base

TARGET SPECIES

Cattle and Pigs

ADMINISTRATION ROUTE

Swine: intramuscular

Cattle: subcutaneous (or intramuscular)

Read the package leaflet before use

WITHDRAWAL PERIOD

Swine: Meat: 2 days

Cattle: Meat: 2 days

 Milk: Nil

 Not for use in bobby calves

Store at or below 25°C. Do not refrigerate or freeze. Protect from light.
Any unused product or waste material should be disposed of in accordance
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