Horses
The safety of ceftiofur has not been determined for horses intended for breeding.
The administration of antimicrobials to horses under conditions of stress may be associated with acute diarrhea that could be fatal. If acute diarrhea is observed, discontinue use of this antimicrobial and initiate appropriate therapy.

Dogs
The safety of ceftiofur has not been determined for dogs intended for breeding, or pregnant dogs.

TO BE PRESCRIBED AND TREATED WITH BY REGISTERED VETERINARY SURGEONS ONLY.

x) Interactions with Other Medicaments
None known.

xi) Pregnancy and lactation
The effects of ceftiofur on the reproductive performance, pregnancy, and lactation of cattle, swine, sheep, and goats have not been determined.
The safety of ceftiofur has not been determined for dogs intended for breeding, or pregnant dogs.

xii) Adverse Effects
The use of ceftiofur may result in some signs of immediate and transient local pain to the animal.

xiii) Symptoms and Treatment of Overdose
None known.

xiv) Withdrawal Period(s)
Cattle:
4-day pre-slaughter withdrawal period when used according to label directions.
When used according to label indications, dosage and routes of administration, a milk discard time is not required.
Use of dosages in excess of those indicated or by unapproved routes of administration, such as intramammary, may result in illegal residues in edible tissues and/or in milk.
Swine:
4-day pre-slaughter withdrawal period when used according to label directions.
Use of dosages in excess of those indicated or by unapproved routes of administration may result in illegal residues in edible tissues.

Sheep and Goats:
Neither a pre-slaughter drug withdrawal interval nor a milk discard time is required when this product is used according to label indications, dosage, and route of administration. Use of dosages in excess of those indicated or by unapproved routes of administration, such as intramammary, may result in illegal residues in edible tissues and/or in milk.
Horses:
Do not use in horses intended for human consumption

xv) Storage Conditions
Store below 30°C (room temperature)

xvi) Shelf-Life as packaged for Sale (powder and solvent)
2 years

Shelf-life after reconstitution

- 7 days - if stored in a refrigerator (2-8°C) or
- 12 hours - if stored at room temperature (below 30°C).

xvii) Dosage Forms and packaging available
Box containing 1 vial containing 1 g of powder + 1 vial containing 20 ml of solvent
Box containing 1 vial containing 4 g of powder + 1 vial containing 80 ml of solvent

xviii) Name and Address of manufacturer and marketing authorisation holder
FATRO S.p.A.
Pharmaceutical Veterinary Industry
Ozzano Emilia (Bologna) Italy

Product Registration Holder
F.E Venture Sdn Bhd.
Lot 3&5, Jalan PJS 11/8, Bandar Sunway,
Petaling Jaya, 46150 Selangor, Malaysia.

xix) Date of Revision of Package Insert
February 2019

wondercef

50 mg/ml
sterile powder for injection

i) Brand or Product Name
WONDERCEF 50 mg/ml sterile powder for injection.

ii) Name and Strength of Active Substance(s)
WONDERCEF 1 g
Vial of powder:
Active substance: ceftiofur sodium……..1105 mg
equivalent to ceftiofur……...1060 mg

Vial of solvent:
water for injections ……20 ml

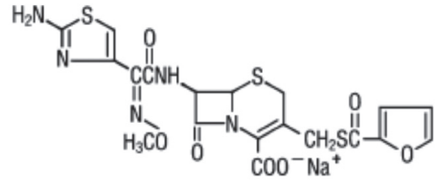
WONDERCEF 4 g
Vial of powder:
Active substance: ceftiofur sodium..……4376 mg
equivalent to ceftiofur……...4200 mg

Vial of solvent:
water for injections……80 ml

Each mL of the reconstituted drug contains ceftiofur sodium equivalent to 50 mg ceftiofur.

iii) Product Description
WONDERCEF contains the sodium salt of ceftiofur which is a broad spectrum cephalosporin antibiotic active against gram-positive and gram-negative bacteria including β-lactamase-producing strains.
Like other cephalosporins, ceftiofur is bactericidal *in vitro*, resulting from inhibition of cell wall synthesis.
Each mL of the reconstituted drug contains ceftiofur sodium equivalent to 50 mg ceftiofur.
The pH was adjusted with sodium hydroxide and mono basic potassium phosphate.

Chemical Structure of Ceftiofur Sodium



Chemical Name of Ceftiofur Sodium
5-Thia-1-azabicyclo[4.2.0]oct-2-ene-2-car boxylic acid, 7-[[(2-amino-4-thiazolyl)(methoxy imino)-acetyl]amino]-3-[[(2-furanylcarbonyl)thio] methyl]-8-oxo-, monosodium salt, [6R-[6a,7ß(Z)]]-

iv) Pharmacodynamics/ Pharmacokinetics
Wondercef Sterile Powder contains sodium ceftiofur, a broad spectrum cephalosporin which is active against Gram-positive and Gram-negative bacteria, including beta-lactamase producing strains.

Ceftiofur has bactericidal activity *in vitro*.
The mode of action is that of cephalosporins, i.e. inhibition of the bacteria cell wall synthesis.

After intramuscular administration ceftiofur is quickly metabolized to desfuroylceftiofur which reaches its maximum plasma concentration within 1 hour. The half-life of desfuroylceftiofur is on average greater than 9 hours in cattle and 13 hours in pigs. No accumulation has been shown after several administrations.

v) Indication
Cattle
WONDERCEF is indicated for treatment of bovine respiratory disease (shipping fever, pneumonia) associated with *Mannheimia haemolytica, Pasteurella multocida* and *Histophilus somni*.

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WONDERCEF is also indicated for treatment of acute bovine interdigital necrobacillosis (foot rot, pododermatitis) associated with *Fusobacterium necrophorum* and *Bacteroides melaninogenicus.*

Swine
WONDERCEF is indicated for treatment/ control of swine bacterial respiratory disease (swine bacterial pneumonia) associated with *Actinobacillus (Haemophilus) pleuropneumoniae, Pasteurella multocida, Salmonella choleraesuis* and *Streptococcus suis.*

Sheep
WONDERCEF is indicated for treatment of sheep respiratory disease (sheep pneumonia) associated with *Mannheimia haemolytica* and *Pasteurella multocida*.

Goats
WONDERCEF is indicated for treatment of caprine respiratory disease (goat pneumonia) associated with *Mannheimia haemolytica* and *Pasteurella multocida*.

Horses
WONDERCEF is indicated for treatment of respiratory infections in horses associated with *Streptococcus zooepidemicus*.

Dogs
WONDERCEF is indicated for the treatment of canine urinary tract infections associated with *Escherichia coli* and *Proteus mirabilis*.

Day-Old Chicks
WONDERCEF is indicated for the control of early mortality, associated with *E. coli* organisms susceptible to ceftiofur, in day-old chicks.

Day-Old Turkey Poults
WONDERCEF is indicated for the control of early mortality, associated with *E. coli* organisms susceptible to ceftiofur, in day-old turkey poults.

vi) Recommended Dosage
Cattle
Administer to cattle by intramuscular or subcutaneous injection at the dosage of 1.1 to 2.2 mg ceftiofur per kg of body weight (1-2 mL reconstituted sterile solution per 45 kg body weight). Treatment should be repeated at 24-hour intervals for a total of three consecutive days. Additional treatments may be given on days four and five for animals which do not show a satisfactory response (not recovered) after the initial three treatments.
Selection of dosage (1.1 to 2.2 mg/kg) should be based on the practitioner's judgement of severity of disease (i.e., for respiratory disease, extent of elevated body temperature, depressed physical appearance, increased respiratory rate, coughing and/or loss of appetite; and for foot rot, extent of swelling, lesion and severity of lameness).

Swine
Administer to swine by intramuscular injection at the dosage of 3.0 to 5.0 mg ceftiofur per kg of body weight (1 mL of reconstituted sterile solution per 10 to 16 kg body weight). Treatment should be repeated at 24-hour intervals for a total of three consecutive days.

Sheep
Administer to sheep by intramuscular injection at the dosage of 1.1 to 2.2 mg ceftiofur per kg of body weight (1-2 mL reconstituted sterile solution per 45 kg body weight).
Treatment should be repeated at 24-hour intervals for a total of three consecutive days. Additional treatments may be given on days four and five for animals which do not show a satisfactory response (not recovered) after the initial three treatments. Selection of dosage (1.1 to 2.2 mg/kg) should be based on the practitioner's judgement of severity of disease (i.e., extent of elevated body temperature, depressed physical appearance, increased respiratory rate, coughing and/or loss of appetite).

Goats
Administer to goats by intramuscular injection at the dosage of 1.1 to 2.2 mg ceftiofur per kg of body weight (1-2 mL reconstituted sterile solution per 45 kg body weight). Treatment should be repeated at 24-hour intervals for a total of three consecutive days. Additional treatments may be given on days four and five for animals which do not show a satisfactory response (not recovered) after the initial three treatments. Selection of dosage (1.1 to 2.2 mg/kg) should be based on the practitioner's judgement of severity of disease (i.e., extent of elevated body temperature, depressed physical appearance, increased respiratory rate, coughing and/or loss of appetite).
Pharmacokinetic data indicate that elimination of the drug is more rapid in lactating does. For lactating does, the high end of the dose range is recommended.

Horses
Administer to horses by intramuscular injection at the dosage of 2.2 to 4.4 mg ceftiofur per kg of body weight (2-4 mL reconstituted sterile solution per 45 kg body weight). A maximum of 10 mL may be administered per injection site. Treatment should be repeated at 24-hour intervals, continued for 48 hours after clinical signs have disappeared and should not exceed 10 days.

Dogs
Administer to dogs by subcutaneous injection at the dosage of 2.2 mg ceftiofur per kg of body weight (0.1 mL reconstituted sterile solution per 2.3 kg body weight). Treatment should be repeated at 24-hour intervals for 5-14 days. Reconstituted WONDERCEF is to be administered to dogs by subcutaneous injection.

Day-Old Chicks
Administer by subcutaneous injection in the neck region of day-old chicks at the dosage of 0.08 to 0.20 mg ceftiofur/chick. One mL of the 50 mg/mL reconstituted solution will treat approximately 250 to 625 day-old chicks. Reconstituted WONDERCEF is to be administered by subcutaneous injection only. A sterile 26 gauge needle and syringe or properly cleaned automatic injection machine should be used.

Day-Old Turkey Poults
Administer by subcutaneous injection in the neck region of day-old turkey poults at the dosage of 0.17 to 0.5 mg ceftiofur/poult. One mL of the 50 mg/mL reconstituted solution will treat approximately 100 to 294 day-old turkey poults. Reconstituted WONDERCEF is to be administered by subcutaneous injection only.

vii) Route of Administration
Intramuscular (IM) or Subcutaneous injection (SC)

RECONSTITUTION OF THE STERILE POWDER
Wondercef Sterile Powder should be reconstituted as follows:
1 gram vial - Reconstitute with 20 mL water for Injection.
Each mL of the resulting solution contains ceftiofur sodium equivalent to 50 mg ceftiofur.
4 gram vial - Reconstitute with 80 mL water for Injection.
Each mL of the resulting solution contains ceftiofur sodium equivalent to 50 mg ceftiofur.
Shake thoroughly prior to use.

viii) Contraindications
As with all drugs, the use of WONDERCEF is contraindicated in animals previously found to be hypersensitive to the drug.

ix) Warnings and Precautions
Keep out of reach of children. For animal use only.

Penicillins and cephalosporins can cause allergic reactions in sensitized individuals. Topical exposures to such antimicrobials, including ceftiofur, may elicit mild to severe allergic reactions in some individuals. Repeated or prolonged exposure may lead to sensitization. Avoid direct contact of the product with the skin, eyes, mouth, and clothing.
Persons with a known hypersensitivity to penicillin or cephalosporins should avoid exposure to this product.
In case of accidental eye exposure, flush with water for 15 minutes.
In case of accidental skin exposure, wash with soap and water. Remove contaminated clothing.
If allergic reaction occurs (e.g., skin rash, hives, difficult breathing), seek medical attention.

PRECAUTIONS
The effects of ceftiofur on the reproductive performance, pregnancy, and lactation of cattle, swine, sheep, and goats have not been determined.

Cattle
Following subcutaneous administration of ceftiofur sodium in the neck, small areas of discoloration at the site may persist beyond five days, potentially resulting in trim loss of edible tissues at slaughter.
As with any parenteral injection, localized post-injection bacterial infections may result in abscess formation. Attention to hygienic procedures can minimize their occurrence.

Swine
The safety of ceftiofur has not been determined for swine intended for breeding.