



Cefēnil[®] **RTU**

(ceftiofur hydrochloride sterile suspension)

Ready-to-use broad spectrum cephalosporin antibiotic for beef cattle

AN ESSENTIAL TOOL TO COMBAT DISEASE



Cefenil[®] RTU
(ceftiofur hydrochloride sterile suspension)

Available in
 100mL and 250 mL sizes

The new and effective alternative to Excenel[®] RTU EZ

Cefenil[®] RTU is approved to treat bovine respiratory disease (BRD), foot rot and acute postpartum metritis in beef cattle. It is the first veterinarian-prescribed generic ceftiofur hydrochloride RTU injectable in the market, and it provides the same effective treatment as Excenel RTU EZ but at a better value.

Features	Cefenil [®] RTU	Excenel [®] RTU EZ
FDA Approved	■	■
Ready-to-Use Formulation	■	■
Multiday Treatment Regimen	■	■
Cost Advantage to Producer	■	

SAME HERD HEALTH PROTOCOLS – IMPROVED VALUE

As a multiday treatment regimen, Cefenil RTU allows you to better monitor recovery to ensure that treatment is working effectively. Cefenil RTU doesn't require any change to your existing protocols so it is a valuable way to treat disease within your operation. And, as the first generic ceftiofur hydrochloride RTU injectable in the market, Cefenil RTU is more affordable, making your investment an even higher value.





DOSING & ADMINISTRATION*

Indication	Administration	Dosage**	Intervals	Additional Treatments
BOVINE RESPIRATORY DISEASE (BRD, shipping fever, pneumonia) Associated with <i>Mannheimia haemolytica</i> , <i>Pasteurella multocida</i> and <i>Histophilus somni</i> .	Intramuscular or subcutaneous	1-2 mL per 100 lbs. bodyweight	Every 24 hours for three consecutive days	Administered on days four and five for animals that have not recovered after initial three treatments
ACUTE BOVINE INTERDIGITAL NECROBACILLOSIS (foot rot, pododermatitis) Associated with <i>Fusobacterium necrophorum</i> and <i>Bacteroides melaninogenicus</i> .	Intramuscular or subcutaneous	1-2 mL per 100 lbs. bodyweight	Every 24 hours for three consecutive days	Administered on days four and five for animals that have not recovered after initial three treatments
ACUTE POSTPARTUM METRITIS (uterine infection) Zero to 14 days postpartum associated with bacterial organisms susceptible to ceftiofur.	Intramuscular or subcutaneous	2 mL per 100 lbs. bodyweight	Every 24 hours for five consecutive days	N/A

*See product labeling for complete dosage and administration options.

**Maximum injection per site 15 mL.

HIGH-QUALITY CARE AT A GREATER VALUE

Cefenil RTU and all generic pharmaceuticals from Norbrook are tested, monitored and proven to provide effective care. Generic products are required to show bioequivalence and achieve the same blood concentration levels of active ingredient as their pioneer products. Generic manufacturing processes are subject to the same FDA regulations as all other pharmaceutical products, making generic products a better value for the same proven and reliable treatment.

To learn more about Cefenil RTU, contact your Norbrook rep or call (866) 591-5777.

Providing quality, cost-effective animal health products for more than 50 years

As one of the largest manufacturers of veterinary sterile injectables and pharmaceuticals in the world, Norbrook is trusted by veterinarians and producers alike. Norbrook is known for their quality products, economical pricing and commitment to providing the best care and enhancing the health of food and companion animals.

Observe label directions and withdrawal times. Not for use in calves to be processed for veal. As with all drugs, the use of Cefenil® RTU (ceftiofur hydrochloride sterile suspension) is contraindicated in animals previously found to be hypersensitive to the drug. See product labeling for full product information.

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Cefenil® RTU

(ceftiofur hydrochloride sterile suspension)

For intramuscular and subcutaneous injection in cattle and intramuscular injection in swine.

This Product May Be Used In Lactating Dairy Cattle.

Not for use in calves to be processed for veal.

Caution: Federal (USA) law restricts this drug to use by or on the order of a licensed veterinarian. Federal law prohibits extra-label use of this drug in cattle and swine for disease prevention purposes; at unapproved doses, frequencies, durations, or routes of administration; and in unapproved major food producing species/production classes.

INDICATIONS

Swine: CEFENIL RTU 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*.

Cattle: CEFENIL RTU is indicated for treatment of the following bacterial diseases:

- Bovine respiratory disease (BRD), shipping fever, pneumonia associated with *Mannheimia haemolytica*, *Pasteurella multocida* and *Histophilus somni*.
- Acute bovine interdigital necrobacillosis (foot rot, pododermatitis) associated with *Fusobacterium necrophorum* and *Bacteroides melaninogenicus*.
- Acute metritis (0 to 14 days post-partum) associated with bacterial organisms susceptible to ceftiofur.

DOSAGE AND ADMINISTRATION

Shake for 90 seconds to ensure complete resuspension before using.

Swine: Administer intramuscularly at a dosage of 1.36 to 2.27 mg ceftiofur equivalents/lb (3.0 to 5.0 mg/kg) BW (1 mL of sterile suspension per 22 to 37 lb BW). Treatment should be repeated at 24 h intervals for a total of three consecutive days.

Cattle: - For bovine respiratory disease and acute bovine interdigital necrobacillosis: administer by intramuscular or subcutaneous administration at the dosage of 0.5 to 1.0 mg ceftiofur equivalents/lb (1.1 to 2.2 mg/kg) BW (1 to 2 mL sterile suspension per 100 lb BW). Administer daily at 24 h intervals for a total of three consecutive days. Additional treatments may be administered on Days 4 and 5 for animals which do not show a satisfactory response (not recovered) after the initial three treatments. In addition, for BRD only, administer intramuscularly or subcutaneously 1.0 mg ceftiofur equivalents/lb (2.2 mg/kg) BW every other day on Days 1 and 3 (48 h interval). Do not inject more than 15 mL per injection site.

Selection of dosage level (0.5 to 1.0 mg/lb) and regimen/duration (daily or every other day for BRD only) should be based on an assessment of the severity of disease, pathogen susceptibility and clinical response.

- For acute post-partum metritis: administer by intramuscular or subcutaneous administration at the dosage of 1.0 mg ceftiofur equivalents/lb (2.2 mg/kg) BW (2 mL sterile suspension per 100 lb BW). Administer at 24 h intervals for five consecutive days. Do not inject more than 15 mL per injection site.

CONTRAINDICATIONS

As with all drugs, the use of CEFENIL RTU is contraindicated in animals previously found to be hypersensitive to the drug.

WARNINGS

NOT FOR HUMAN USE. KEEP OUT OF REACH OF CHILDREN.

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.

RESIDUE WARNINGS:

Swine: When used according to label indications, dosage, and route of administration, treated swine must not be slaughtered for 4 days following the last treatment.

Use of dosages in excess of those indicated or by unapproved routes of administration may result in illegal residues in edible tissues.

Cattle: When used according to label indications, dosage and route of administration, treated cattle must not be slaughtered for 3 days following the last treatment. When used according to label indications, dosage and route of administration, a milk discard time is not required. Uses 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 milk. A withdrawal period has not been established in pre-ruminating calves. Do not use in calves to be processed for veal.

PRECAUTIONS

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

Swine: Areas of discoloration associated with the injection site at time periods of 11 days or less may result in trim-out of edible tissues at slaughter. The safety of ceftiofur has not been demonstrated for pregnant swine or swine intended for breeding.

Cattle: Following intramuscular or subcutaneous administration in the neck, areas of discoloration at the site may persist beyond 11 days resulting in trim loss of edible tissues at slaughter. Following intramuscular administration in the rear leg, areas of discoloration at the injection site may persist beyond 28 days resulting in trim loss of edible tissues at slaughter.

STORAGE CONDITIONS

Do not store above 30°C (86°F). Shake well before using. Protect from freezing. Contents should be used within 42 days after the first dose is removed.

HOW SUPPLIED

CEFENIL RTU is available in 100 mL and 250 mL vials.

The safety data sheet contains more detailed occupational safety information. To report suspected adverse drug events, for technical assistance or to obtain a copy of the safety data sheet (SDS), contact Norbrook at 1-866-591-5777. For additional information about adverse drug experience reporting for animal drugs, contact FDA at 1-888-FDA-VETS or online at www.fda.gov/reportanimalae.

Approved by FDA under ANADA # 200-616

Made in the UK

Manufactured by: Norbrook Laboratories Limited, Newry, Co. Down, BT35 6PU, Northern Ireland

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