FRESH-COW CARE is a high priority at the Van Ess dairy in Middleton, Idaho.

Managing fresh cows to keep productivity high

Catching fresh-cow problems early helps minimize clinical effects of metritis – and treatment with EXCENEL® RTU Sterile Suspension keeps milk in the tank.

Looking into the fresh-cow pen, Harvey and Lisa Van Ess see the cows that represent the greatest income potential for their family's dairy.

"A healthy fresh cow is a profitable cow," say Harvey and Lisa, who operate a 1,200-cow dairy in Middleton, Idaho. "You absolutely cannot cut corners when it comes to fresh cows."

They speak from experience. Faced with a rolling herd average that had plateaued at 28,000 pounds, the Van Esses were searching for a way to increase milk production. The Van Esses consulted with Earl Aalseth, DVM, of Pilchuck Veterinary Hospital in Snohomish, Wash., and took his recommendation to begin an intensive fresh-cow program.

Dedicated facilities required

The Van Esses now have a dedicated fresh-cow pen and take daily rectal temperatures of every cow for a full 10 days after calving. The electronic thermometer allows them to quickly identify and treat disorders such as metritis. Any cow with a temperature above 103 degrees F is given EXCENEL® RTU Sterile Suspension (ceftiofur hydrochloride) for at least three days.

Since making fresh-cow care a top priority, the Van Esses' herd health is "the best it has ever been," says Lisa. "When cows leave the fresh pen, they are healthy."

Before the change in fresh-cow monitoring, 15 to 20 cows that were more than 30 days in milk had to be treated for uterine infections at each biweekly vet check, Aalseth recalls.

"Now it's rare for the Van Esses to have to treat for metritis and pyometra once cows are in the lactating string," he comments. "Death losses have dropped from about 7 to 8 percent during

Fresh-cow protocol offers early diagnosis, timely intervention

Pharmacia Animal Health has developed a fresh-cow protocol designed to identify fevers and other ailments as soon as day one post-calving, preventing significant health problems from developing later. This protocol is the cornerstone of the 100-Day Contract℠ Dairy Wellness Plan, a revolutionary dairy management program, which optimizes early pregnancies by focusing on the critical period of 30 days before calving to 70 days after.

For more information about the 100-Day Contract, contact your Pharmacia Animal Health representative or visit www.100daycontract.com.

the first six months of 2000, to 3 to 4 percent for the same period in 2001. The cull rate is also down from 37 percent to 22 percent."

Production jumped dramatically

Paying more attention to fresh cows also boosted production. "Our rolling herd average has increased by at least 2,000 pounds," says Lisa.

By using EXCENEL RTU, the Van Esses minimize the complications of metritis, such as cows going off-feed and declining milk production. They also have no residue worries, since EXCENEL RTU requires zero milk discard when used as directed.

Aalseth emphasizes that daily temperature monitoring is essential to catch metritis cases early in order to keep cows out of the hospital pen.

"The sicker an animal is the more drugs you use, but the effect is less," says Aalseth. "EXCENEL RTU is most successful when used on a metritis case that's found on the first detectable day."

The approved EXCENEL RTU treatment regimen for metritis is daily administration of 2 mL/100 pounds body weight by intramuscular or subcutaneous injection, repeated at 24-hour intervals for five consecutive days. As with all drugs, EXCENEL RTU should not be used in animals found to be hypersensitive to the product.

Quick action pays its way

Curing cows quickly also helps the Van Ess operation avoid these costly byproducts of acute clinical metritis:

- Prolonged days open, due to lower conception and estrous detection rates
- Increased culling rate, resulting in higher replacement costs
- Higher insemination costs, due to repeat AI services
- Greater costs for veterinary interventions, plus income lost from milk that must be discarded using extra-label therapies

"Good uterine health is critical to launching cows on to a healthy, productive lactation after calving," Lisa emphasizes. "We're very aggressive in treating cows with EXCENEL RTU because we don't want to get behind the eight ball.

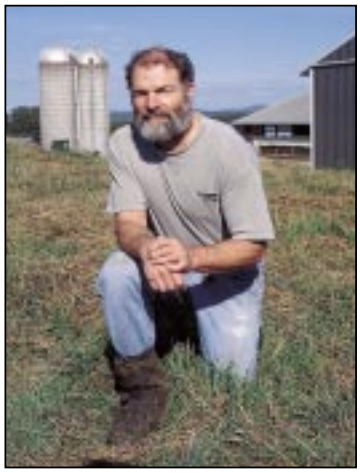
"Our treatment costs have increased since starting this program, but our cull rate has been sliced in half. We've saved $24,000 in six months on replacement costs."

Look at the total costs

George Allen of Fairmont Farm in Vermont also makes EXCENEL RTU his antibiotic of choice for treating metritis. As the fresh-cow manager for this 600-cow dairy in East Montpelier, he knows the challenges of keeping fresh cows healthy in a cost-effective way. Using Pharmacia Animal Health's 100-Day Contract℠ Dairy Wellness Plan and temping all cows for 10 days after calving identifies problem cows as early as possible for the most effective treatment.

"To get the most value from this fresh-cow health program, we look at returns and not just treatment costs," he says. "We use EXCENEL RTU because it's easy to use, effective and because it makes the most financial sense. EXCENEL RTU doesn't have any milk withdrawal, so we're not dumping milk. That gives us more return than with other antibiotics in treating metritis.

"EXCENEL RTU also eliminates the anxiety that treated milk might end up in the tank. There are no antibiotic residue worries," Allen notes. "If milk from treated cows were to get in the tank, we'd have to dump about 60,000 pounds of milk. That's scary."



George Allen

Know your costs

Mike and Zeba Schouten

Mike Schouten, owner of three dairies in Hico, Texas, agrees that you can't accurately analyze fresh-cow treatment costs unless you track your returns along with your costs.

"Unless you record, track and benchmark, there is no way to visualize how fresh-cow treatments add value to the operation," he says.

After analyzing his records, Schouten determined that his fresh-cow program needed the most improvement. Schouten aggressively developed management procedures with his team of professional advisers. Working with the on-farm team, the Texas dairy adopted the 100-Day Contract℠ fresh-cow protocols and outlined steps for early identification and treatment of all health and metabolic problems.

Schouten now is convinced that temperature monitoring of all fresh cows is an important tool in catching cows that need extra attention and treatment – before they reach a more critical stage.

"Temping is very effective and necessary for early detection of disorders, including metritis in fresh cows," he says.

PHARMACIA Animal Health

EXCENEL® RTU

NDC 0009-3504-03

brand of ceftiofur hydrochloride sterile suspension

For intramuscular and subcutaneous use in cattle. This product may be used in lactating dairy cattle.

CAUTION: Federal (USA) law restricts this drug to use by or on the order of a licensed veterinarian.

DESCRIPTION

EXCENEL RTU Sterile Suspension is a ready to use formulation that contains the hydrochloride salt of ceftiofur, which is a broad spectrum cephalosporin antibiotic.

Each mL of this ready-to-use sterile suspension contains ceftiofur hydrochloride equivalent to 50 mg ceftiofur, 0.50 mg phospholipon, 1.5 mg sorbitan monooleate and cottonseed oil.

Structure:

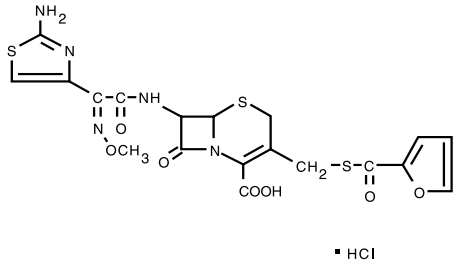


Figure 1

Chemical Name of Ceftiofur Hydrochloride: 5-Thia-1-azabicyclo[4,2.0]oct-2-ene-2-carboxylic acid, 7-[[(2-amino-4-thiazolyl)(methoxyimino)-acetyl]amino]-3-[[(2-furanylcarbonyl) thio]methyl]-8-oxo-,hydrochloride salt [6R-[6α,7β(Z)]]-

CLINICAL PHARMACOLOGY

Ceftiofur administered as either ceftiofur sodium or ceftiofur hydrochloride is metabolized rapidly to desfuroylceftiofur, the primary metabolite. Administration of ceftiofur to cattle as either the sodium or hydrochloride salt provides effective concentrations of ceftiofur and desfuroylceftiofur metabolites in plasma above the MIC_{90} for the bovine respiratory disease (BRD) label pathogens *Pasteurella haemolytica (Mannheimia* spp.*), Pasteurella multocida* and *Haemophilus somnus* for at least 48 h. The relationship between plasma concentrations of ceftiofur and desfuroylceftiofur metabolites above the MIC_{90} in plasma and efficacy has not been established for the treatment of bovine interdigital necrobacillosis (foot rot) associated with *Fusobacterium necrophorum* and *Bacteroides melaninogenicus.*

Comparative Bioavailability Summary

The comparability of plasma concentrations of ceftiofur following administration of ceftiofur hydrochloride sterile suspension (EXCENEL RTU Sterile Suspension) or ceftiofur sodium sterile solution (NAXCEL® Sterile Powder) was demonstrated after intramuscular or subcutaneous administration of ceftiofur hydrochloride and intramuscular administration of ceftiofur sodium at 1.0 mg ceftiofur equivalents/lb (2.2 mg/kg) BW. See Table 1 and Figure 2.

Table 1. Cattle plasma concentrations and related parameters of ceftiofur and desfuroylceftiofur metabolites after EXCENEL RTU Sterile Suspension (ceftiofur hydrochloride sterile suspension, 50 mg/mL) administered intramuscularly or subcutaneously at 1.0 mg ceftiofur equivalents/lb (2.2 mg/kg) BW and NAXCEL Sterile Powder (ceftiofur sodium sterile powder, 50 mg/mL) administered intramuscularly at 1.0 mg ceftiofur equivalents/lb (2.2 mg/kg) BW.

	Ceftiofur hydrochloride		Ceftiofur sodium
	IM	SC	IM[1]
C_{max} µg/mL	11.0 ± 1.69	8.56 ± 1.89	14.4–16.5
t_{max} h	1–4 (range)	1–5 (range)	0.33–3.0
$t_{>0.2}$ h	60.5 ± 6.27	51.0 ± 6.53	50.7–50.9
$AUC_{0\text{-}LOQ}$ µg • h/mL	160 ± 30.7	95.4 ± 17.8	115–142
$t_{1/2}$ h	12.0 ± 2.63	11.5 ± 2.57	9.50–11.1
$C_{24\ h}$ µg/mL	1.47 ± 0.380	0.926 ± 0.257	0.86–1.16
$C_{48\ h}$ µg/mL	0.340 ± 0.110	0.271 ± 0.086	0.250–0.268

Definitions:

C_{max} – maximum concentration of drug in plasma in µg/mL

t_{max} – the time after initial injection to when C_{max} occurs, measured in hours

$t_{>0.2}$ – the time (in hours) plasma drug concentrations remain above 0.2 µg/mL

$AUC_{0\text{-}LOQ}$ – the area under the plasma drug concentration vs. time curve from time of injection to the limit of quantitation of the assay (0.15 µg/mL)

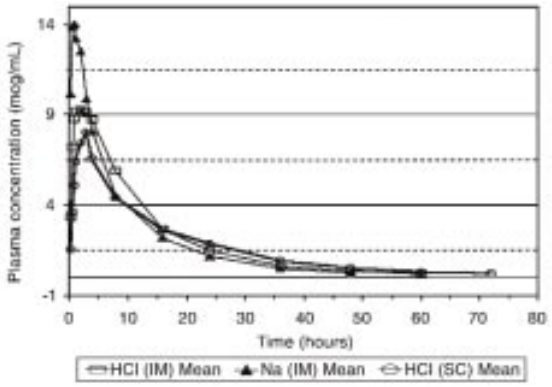
$t_{1/2}$ – the drug half life in plasma expressed in hours

$C_{24\ h}$ – the plasma drug concentration 24 h after administration

$C_{48\ h}$ – the plasma drug concentration 48 h after administration

[1]Values represent the separate means from each study.

Figure 2. Cattle plasma concentrations of ceftiofur and desfuroylceftiofur metabolites after administration of 1.0 mg ceftiofur equivalents/lb (2.2 mg/kg) BW of EXCENEL RTU Sterile Suspension (ceftiofur hydrochloride sterile suspension, 50 mg/mL) by intramuscular or subcutaneous injection or NAXCEL Sterile Powder (ceftiofur sodium sterile powder, 50 mg/mL) by intramuscular injection.



Total residues of ceftiofur were measured in the lungs of cattle administered radiolabeled ceftiofur at 1.0 mg ceftiofur equivalents/lb (2.2 mg/kg) BW at 24 h intervals for five consecutive days. Twelve h after the fifth injection of ceftiofur hydrochloride, total ceftiofur concentrations in the lung averaged 1.15 µg/g, while total ceftiofur concentrations in the lung 8 h after the fifth ceftiofur sodium injection averaged 1.18 µg/g.

MICROBIOLOGY

EXCENEL RTU Sterile Suspension is a ready to use formulation that contains the hydrochloride 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 bacteriocidal, *in vitro*, resulting in inhibition of cell wall synthesis.

In vitro activity has been demonstrated for ceftiofur against gram-positive organisms such as *Actinomyces pyogenes*, and other gram-negative organisms, such as *Escherichia coli* and *Salmonella typhimurium*. Ceftiofur was effective when tested in a variety of mouse disease models involving *Escherichia coli, Pasteurella multocida,* and *Salmonella typhimurium*. MIC_{90} values for ceftiofur against other pathogens are as follows: *Salmonella typhimurium* (98 isolates), 2.0 µg/mL; *Escherichia coli* (94 isolates), 1.0 µg/mL. The clinical significance of these findings is not known.

Cattle: Studies with ceftiofur have demonstrated *in vitro* and *in vivo* activity against *Mannheimia* spp. (*Pasteurella haemolytica), Pasteurella multocida* and *Haemophilus somnus*, the three major pathogenic bacteria associated with bovine respiratory disease (BRD, pneumonia, shipping fever). A summary of MIC data for BRD pathogens is provided in Table 2.

Studies with ceftiofur have demonstrated *in vitro* and *in vivo* activity against *Fusobacterium necrophorum* and *Bacteroides melaninogenicus,* two of the major pathogenic anaerobic bacteria associated with acute bovine interdigital necrobacillosis (foot rot, pododermatitis).

Antimicrobial Susceptibility

A summary of MIC data for cattle (1993-1994) pathogens is presented in Table 2. Clinical isolates were obtained in the United States. Testing followed NCCLS Guidelines (National Committee for Clinical Laboratory Standards).

Table 2. Minimum Inhibitory Concentrations for Ceftiofur Against BRD Clinical Isolates

		MIC µg/mL	
Organism (# of strains tested)	**Range**	**MIC_{90}**	**Date Tested**
Cattle			
Mannheimia spp. **(Pasteurella haemolytica)* (42)	≤0.003 – 0.03	0.015	1993
**Pasteurella multocida* (48)	≤0.003 – 0.015	≤0.003	1993
**Haemophilus somnus* (59)	no range	≤0.0019	1993
**Fusobacterium necrophorum* (17)	≤0.06	≤0.06	1994
***Bacteroides fragilis* group (29)	≤0.06 – >16.0	16.0	1994
***Bacteroides* spp. non-fragilis group (12)	0.13 - >16.0	16.0	1994
***Peptostreptococcus anaerobius* (12)	0.13 - 2.0	2.0	1994

* Clinical isolates supported by clinical data and indications for use.

** Clinical isolates not supported by clinical data, the clinical significance of these data is not known.

MIC_{90} Minimum inhibitory concentration for 90% of the isolates.

Based on the pharmacokinetic studies of ceftiofur in cattle after a single intramuscular injection of 0.5 to 1.0 mg ceftiofur equivalents/lb (1.1 to 2.2 mg/kg) BW (cattle) and the MIC and disk (30 µg) diffusion data, the following breakpoints are recommended by NCCLS.

Zone Diameter (mm)	MIC (µg/mL)	Interpretation
≥ 21	≤ 2.0	(S) Susceptible
18-20	4.0	(I) Intermediate
≤ 17	> 8.0	(R) Resistant

A report of "Susceptible" indicates that the pathogen is likely to be inhibited by generally achievable blood levels. A report of "Intermediate" is a technical buffer zone and isolates falling into this category should be retested. Alternatively the organism may be successfully treated if the infection is in a body site where drug is physiologically

concentrated. A report of "Resistant" indicates that the achievable drug concentrations are unlikely to be inhibitory and other therapy should be selected.

Standardized procedures[1] require the use of laboratory control organisms for both standardized diffusion techniques and standardized dilution techniques. The 30 µg ceftiofur sodium disk should give the following zone diameters and the ceftiofur sodium standard reference powder (or disk) should provide the following MIC values for the reference strain. Ceftiofur sodium disks or powder reference standard is appropriate for both ceftiofur salts.

QC Strain	MIC (µg/mL)	Disk Zone Diameter (mm)
E. coli ATCC 25922	0.25-1	24-30

CLINICAL EFFICACY

In addition to demonstrating comparable plasma concentrations, the following clinical efficacy data are provided.

A clinical study was conducted to evaluate the efficacy of ceftiofur hydrochloride administered subcutaneously for the treatment of the bacterial component of BRD under natural field conditions. When uniform clinical signs of BRD were present, 60 cattle (111 to 207 kg) were randomly assigned to one of the following treatment groups: negative control or ceftiofur hydrochloride at 0.5 or 1.0 ceftiofur equivalents/lb (1.1 or 2.2 mg/kg) BW. Treatments were administered daily for three consecutive days. Cattle were evaluated daily and animals that died or were euthanatized were necropsied and the lung lesions scored. On Day 15, all surviving animals were euthanatized and necropsied and the lung lesions scored. Mortality rates were 65%, 10% and 5% for negative controls, 0.5 mg ceftiofur equivalents/lb and 1.0 mg ceftiofur equivalents/lb, (1.1 or 2.2 mg/kg) BW, respectively. Mortality rates for both ceftiofur hydrochloride treatment groups were lower than for negative controls ($P < 0.0001$). Rectal temperatures 24 h after third treatment were 104.0°F, 103.1°F and 102.8°F for negative controls, 0.5 mg/lb and 1.0 mg/lb (1.1 or 2.2 mg/kg) BW, respectively. The temperatures for both ceftiofur hydrochloride treatment groups were lower than the negative controls ($P \leq 0.05$). Ceftiofur hydrochloride administered subcutaneously for three consecutive days at 0.5 or 1.0 mg ceftiofur equivalents/lb (1.1 or 2.2 mg/kg) BW is an effective treatment for the bacterial component of BRD.

A three-location clinical field study was conducted to evaluate the efficacy of ceftiofur hydrochloride administered intramuscularly daily for three days or every other day (Days 1 and 3) for the treatment of the bacterial component of naturally occurring BRD. When uniform signs of BRD were present, 360 beef crossbred cattle were randomly assigned to one of the following treatment groups: negative control, ceftiofur sodium at 0.5 mg ceftiofur equivalents/lb (1.1 mg/kg) BW daily for three days, ceftiofur hydrochloride at 1.0 mg ceftiofur equivalents/lb (2.2 mg/kg) BW daily for three days, or ceftiofur hydrochloride at 1.0 mg ceftiofur equivalents/lb BW on Days 1 and 3 (every other day). All treatments were administered intramuscularly. All ceftiofur treatment groups (hydrochloride and sodium) and treatment regimens (every day and every other day) significantly ($P < 0.05$) reduced Day 4 rectal temperature as compared to the negative control. Clinical success on Days 10 and 28 and mortality to Day 28 were not different for the ceftiofur groups (hydrochloride and sodium) and treatment regimens (every day and every other day). The results of this study demonstrate that daily and every other day (Days 1 and 3) intramuscular administration of ceftiofur hydrochloride are effective treatment regimens for the bacterial component of BRD.

An eight location study was conducted under natural field conditions to evaluate the efficacy of ceftiofur hydrochloride for the treatment of acute post-partum metritis. When clinical signs of acute post-partum metritis (rectal temperature ≥ 103°F and fetid vaginal discharge) were observed, 361 lactating dairy cows were assigned randomly to treatment or negative control. Cattle were dosed either subcutaneously or intramuscularly, daily for five consecutive days. On days 1, 5 and 9 after the last day of dose administration, cows were evaluated for clinical signs of acute post-partum metritis. A cure was defined as rectal temperature < 103°F and lack of fetid discharge. Cure rate for the 1.0 mg ceftiofur equivalents/lb (2.2 mg/kg) BW dose group was significantly improved relative to cure rate of the negative control on day 9. The results of this study demonstrate that ceftiofur hydrochloride administered daily for five consecutive days at a dose of 1.0 mg ceftiofur equivalents/lb (2.2 mg/kg) BW is an effective treatment for acute post-partum metritis.

ANIMAL SAFETY

Results from a five-day tolerance study in feeder calves indicated that ceftiofur sodium was well tolerated at 25 times (25 mg ceftiofur equivalents/lb {55 mg/kg} BW) the highest recommended dose of 1.0 mg ceftiofur equivalents/lb (2.2 mg/kg) BW for five consecutive days. Ceftiofur administered intramuscularly had no adverse systemic effects.

In a 15-day safety/toxicity study, five steer and five heifer calves per group were administered ceftiofur sodium intramuscularly at 0 (vehicle control), 1, 3, 5 and 10 times the highest recommended dose of 1.0 mg ceftiofur equivalents/lb (2.2 mg/kg) BW to determine the safety factor. There were no adverse systemic effects indicating that ceftiofur sodium has a wide margin of safety when injected intramuscularly into the feeder calves at 10 times (10 mg ceftiofur equivalents/lb {22 mg/kg} BW) the recommended dose for three times (15 days) the recommended length of treatment of three to five days. Local tissue tolerance to intramuscular injection of ceftiofur hydrochloride was evaluated in the following study.

Results from a tissue tolerance study indicated that ceftiofur hydrochloride was well tolerated and produced no systemic toxicity in cattle when administered intramuscularly in the neck and rear leg at a dose of 1.0 mg ceftiofur equivalents/lb (2.2 mg/kg) BW at each injection site. This represents a total dose per animal of 2.0 mg ceftiofur equivalents/lb (4.4 mg/kg) BW. Clinically noted changes (local swelling) at injection sites in the neck were very infrequent (2/48 sites) whereas noted changes in rear leg sites were more frequent (21/48 sites). These changes in the rear leg injection sites were generally evident on the day following injection and lasted from 1 to 11 days. At necropsy, injection sites were recognized by discoloration of the subcutaneous tissues and muscle that resolved in approximately 7 to 15 days in the neck and 19 to 28 days in the rear leg.

[1] National Committee for Clinical Laboratory Standards. Performance Standards for Antimicrobial Disk and Dilution Susceptibility Tests for Bacteria Isolated from Animals; Proposed Standard. NCCLS Document M31-P (ISBN 1-56238-258-6). NCCLS, 771 East Lancaster Avenue, Villanova, Pennsylvania 19085, 1994.

Results from another tissue tolerance study indicated that ceftiofur hydrochloride was well tolerated and produced no systemic toxicity to cattle when administered subcutaneously at 0.5 or 1.0 mg ceftiofur equivalents/lb (1.1 or 2.2 mg/kg) BW at 24 h intervals for 5 days. Mild and usually transient, clinically visible or palpable reactions (local swelling) were localized at the injection site. At necropsy, injection sites were routinely recognized by edema, limited increase in thickness and color changes of the subcutaneous tissue and/or facial surface of underlying muscle. The facial surface of the muscle was visibly affected in most cases through 9.5 days after injection. Underlying muscle mass was not involved. There were no apparent differences in tissue response to administration of ceftiofur hydrochloride at 0.5 or 1.0 mg ceftiofur equivalents/lb (1.1 or 2.2 mg/kg) BW.

INDICATIONS

EXCENEL RTU Sterile Suspension is indicated for treatment of the following bacterial diseases:

– Bovine respiratory disease (BRD, shipping fever, pneumonia) associated with *Mannheimia* spp. *(Pasteurella haemolytica), Pasteurella multocida* and *Haemophilus somnus*.

– 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.

CONTRAINDICATIONS

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

DOSAGE AND ADMINISTRATION

– For bovine respiratory disease and acute 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.

Shake well before using.

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.

The material safety data sheet contains more detailed occupational safety information. To report adverse effects in users, to obtain more information or obtain a material safety data sheet, call 1-800-253-8600.

RESIDUE WARNINGS: Treated cattle must not be slaughtered for 48 hours (2 days) following last treatment because unsafe levels of drug remain at the injection sites. No milk discard time is required when this product is used according to label directions. 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. A withdrawal period has not been established in pre-ruminating calves. Do not use in calves to be processed for veal.

PRECAUTIONS

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

Store at controlled room temperature 20° to 25° C (68° to 77° F) [see USP]. Shake well before using. Protect from freezing.

HOW SUPPLIED

EXCENEL RTU Sterile Suspension is available in the following package size:

100 mL vial NDC 0009-3504-03

NADA #140-890, Approved by FDA

U.S. Patent Nos. 4,902,683; 5,736,151

Pharmacia & Upjohn Company • Kalamazoo, MI 49001, USA

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