

WHY WOULD ANYBODY
AIM FOR

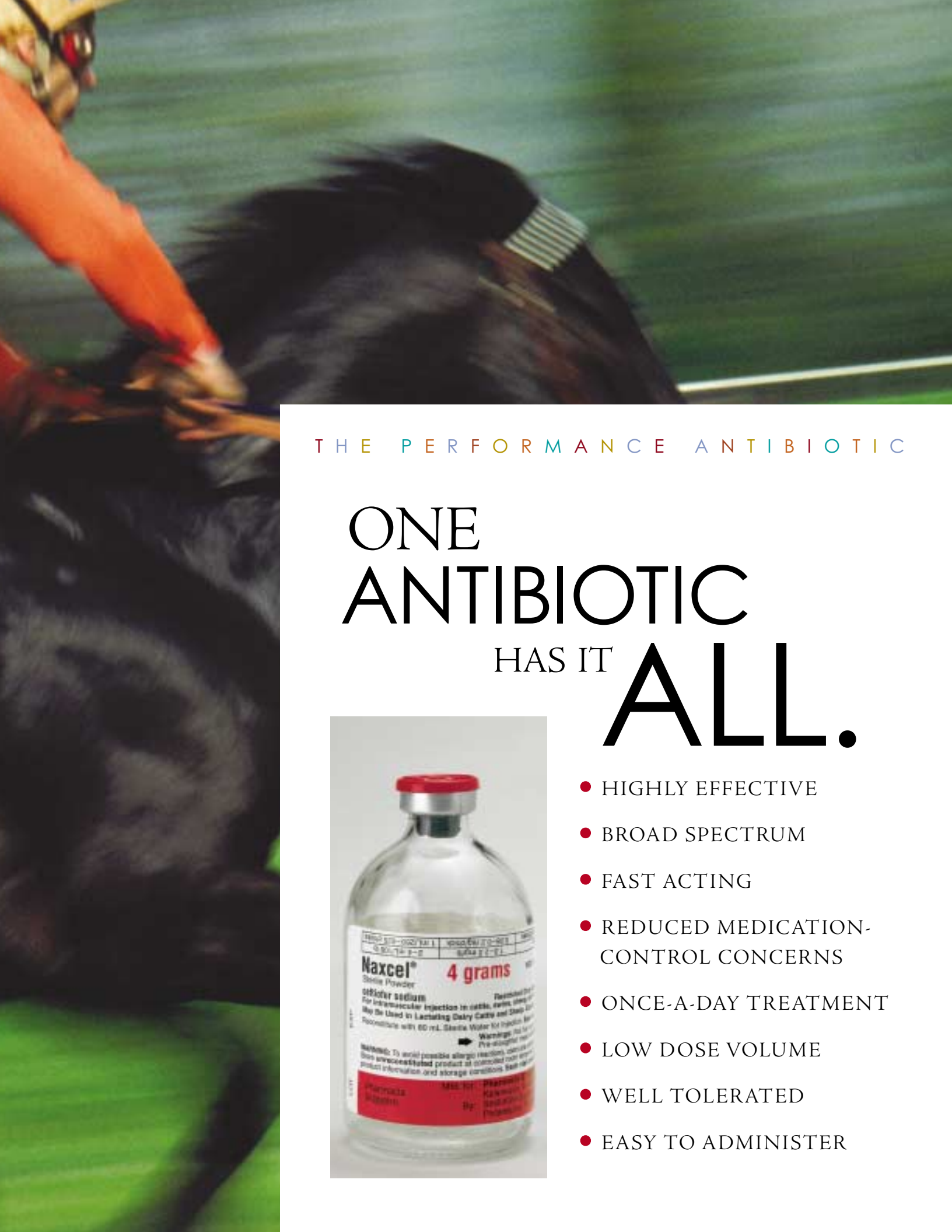


GOOD
ENOUGH?

THE PERFORMANCE ANTIBIOTIC

NAXCEL[®]
Sterile Powder
(ceftiofur sodium)





THE PERFORMANCE ANTIBIOTIC

ONE ANTIBIOTIC HAS IT **ALL.**



- HIGHLY EFFECTIVE
- BROAD SPECTRUM
- FAST ACTING
- REDUCED MEDICATION-CONTROL CONCERNS
- ONCE-A-DAY TREATMENT
- LOW DOSE VOLUME
- WELL TOLERATED
- EASY TO ADMINISTER



T H E P E R F O R M A N C E A N T I B I O T I C

GET THEM BACK IN

WINNING FORM FAST.

Whether for racing or recreation, a horse is a substantial investment. When it comes

to choosing an antibiotic, every horse deserves the efficacy and security of a high-performance treatment. Every horse deserves

NAXCEL® Sterile Powder (ceftiofur sodium).

REDUCED MEDICATION-CONTROL CONCERNS.

- **NAXCEL** Sterile Powder contains the sodium salt of ceftiofur and is reconstituted with sterile water.
- Unlike other commonly used antibiotics, which may unnecessarily delay return to competition, **NAXCEL** contains no procaine, benzathine or primary sulfa components.

HIGHLY EFFECTIVE BROAD SPECTRUM.

- **NAXCEL** is indicated for treatment of equine respiratory infections due to *Streptococcus zooepidemicus*. Ceftiofur, the active ingredient in **NAXCEL**, has also been shown to be active against other gram-positive and gram-negative pathogens.
- In a blinded, well-controlled clinical study, 60 horses with naturally acquired respiratory infections were randomly assigned to 2 study groups: **NAXCEL** administered at 1 mg/lb (2.2 mg/kg) once a day (SID) intramuscularly (IM) or saline administered at the same volume.¹
 - 93% (28) of the horses treated with **NAXCEL** showed clinical improvement on the last day of treatment.
 - Body temperature reduction was significantly greater for the group treated with **NAXCEL** than for the control group after 2 treatments ($P < 0.01$).
 - One week after the last treatment, 26 horses treated with **NAXCEL** were completely recovered.

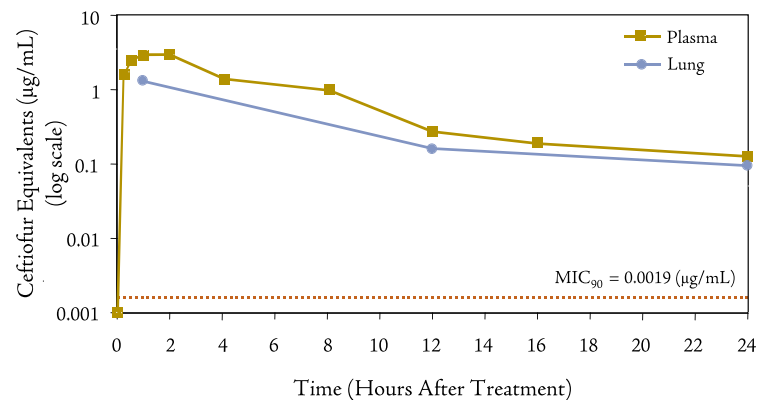
The table at right shows minimum inhibitory concentration (MIC) values for ceftiofur against *Streptococcus zooepidemicus*.

Organism	No. Strains	Ceftiofur MIC (µg/mL)
<i>S. zooepidemicus</i>	48	
MIC ₉₀		≤0.0019
MIC range		≤0.0019

FAST ACTION.

- **NAXCEL** reaches therapeutic blood levels within minutes.
- **NAXCEL** is absorbed quickly, with average maximum concentrations occurring in plasma and lungs 1.25 hours after administration.²
- 24 hours after administration **NAXCEL** concentrations in plasma and lungs exceed the minimum inhibitory concentration.

Mean plasma and lung levels of desfuroylceftiofur ($\mu\text{g}/\text{mL}$ ceftiofur equivalents) in horses following a single intramuscular dose of 2.2 mg/kg (1 mg/lb) body weight.³



SAFETY.

- In a multicenter, well-controlled trial with **NAXCEL** in horses with naturally acquired respiratory disease:¹
 - There was no evidence of pain or swelling at the injection sites.
 - Diarrhea was not observed in any of the treated horses at the labeled dose.
- As with all drugs, **NAXCEL** should not be used in animals found to be hypersensitive to the product.

EASE OF USE.

- Once-a-day treatment means convenience for you and less stress on the horse.
- **NAXCEL** should be administered IM.

NAXCEL®

NDC 0009-3362-03, NDC 0009-3362-04

brand of ceftiofur sodium sterile powder

For intramuscular injection in horses.

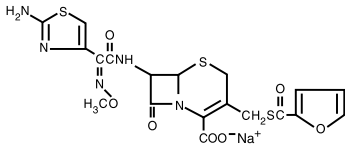
CAUTION: Federal (USA) law restricts this drug to use by or on the order of a licensed veterinarian.

DESCRIPTION

NAXCEL Sterile Powder 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 monobasic potassium phosphate.

Chemical Structure of Ceftiofur Sodium



Chemical Name of Ceftiofur Sodium

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-, monosodium salt, [6R-[6 α ,7 β (Z)]]-

RECONSTITUTION OF THE STERILE POWDER

NAXCEL Sterile Powder should be reconstituted as follows:

1 gram vial — Reconstitute with 20 mL Sterile Water for Injection. Each mL of the resulting solution contains ceftiofur sodium equivalent to 50 mg ceftiofur.

4 gram vial — Reconstitute with 80 mL Sterile Water for Injection. Each mL of the resulting solution contains ceftiofur sodium equivalent to 50 mg ceftiofur.

STORAGE CONDITIONS

Store **unreconstituted** product at controlled room temperature 20° to 25° C (68° to 77° F) [see USP].

Store **reconstituted** product either in a refrigerator 2° to 8° C (36° to 46° F) for up to 7 days or at controlled room temperature 20° to 25° C (68° to 77° F) [see USP] for up to 12 hours.

Reconstituted NAXCEL Sterile Powder can be frozen for up to 8 weeks without loss in potency or other chemical properties. Carefully thaw the frozen material under warm to hot running water, gently swirling the container to accelerate thawing. The frozen material may also be thawed at room temperature.

Protect from light. Color of the cake may vary from off-white to a tan color. Color does not affect potency.

CLINICAL MICROBIOLOGY

Horses	Organism	n	MIC Range (mcg/mL)	MIC ₉₀ (mcg/mL)	Date tested
	<i>Streptococcus equi</i> subsp. <i>equi</i>	12	≤0.0019	≤0.0019	1994
	<i>Streptococcus zooepidemicus</i>	48	≤0.0019	≤0.0019	1994
*	<i>Rhodococcus equi</i>	67	≤0.03-2.0	8.0	1998
	<i>Bacteroides fragilis</i> group	32	0.13->16.0	>16.0	1995
	<i>Bacteroides</i> spp. non-fragilis group	12	0.25-4.0	4.0	1995
	<i>Fusobacterium necrophorum</i>	16	≤0.06	≤0.06	1995

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

MIC₉₀ Minimum inhibitory concentration for 90% of the isolates.

n Number of isolates.

HORSE USE INFORMATION

Indications

NAXCEL Sterile Powder is indicated for treatment of respiratory infections in horses associated with *Streptococcus zooepidemicus*.

Dosage and Administration

Administer to horses at a dosage of 1.0 to 2.0 mg ceftiofur per pound of body weight (2–4 mL reconstituted sterile solution per 100 lb 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.

Animal Safety

In a safety study, horses received a daily intramuscular injection of either 0 mg/lb/day (saline control), 1.0 mg/lb/day (50 mg/mL), 3.0 mg/lb/day (100 mg/mL), or 5.0 mg/lb/day (200 mg/mL) of an aqueous solution of ceftiofur sodium for 30 or 31 days. Ceftiofur sodium was well tolerated when administered intramuscularly to male and female horses at doses up to 5.0 mg/lb/day for 30 or 31 days. No clinical evidence of irritation was noted at any dose. The drug-related changes detected in this study were limited to a transient decrease in food consumption in horses receiving 3.0 or 5.0 mg/lb/day ceftiofur, and general mild skeletal muscle irritation at the injection sites which resolved by regeneration of muscle fibers.

In a tolerance study, horses received a single daily intravenous infusion of either 0 (saline), 10.0 or 25.0 mg/lb/day of an aqueous solution (50 mg/mL) of ceftiofur for 10 days. The results indicated that ceftiofur administered intravenously at a dose of 10.0 or 25.0 mg/lb/day apparently can change the bacterial flora of the large intestine thereby leading to inflammation of the large intestine with subsequent diarrhea and other clinical signs (loose feces, eating bedding straw, dehydration, rolling or colic and a dull, inactive demeanor). Decreased food consumption, a loss of body weight, hematologic changes related to acute inflammation and stress, and serum chemistry changes related to decreased food consumption and diarrhea were also associated with treatment at these doses. The adverse effects were most severe a few days after dosing was initiated and tended to become less severe toward the end of the 10-day dosing period.

Residue Warnings: Not for use in horses intended for human consumption.

Precautions

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.

CONTRAINDICATIONS

As with all drugs, the use of NAXCEL Sterile Powder 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.

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.

ADVERSE REACTIONS

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

HOW SUPPLIED

NAXCEL Sterile Powder is available in the following package sizes:

1 gram vial NDC 0009-3362-03

4 gram vial NDC 0009-3362-04

NADA # 140-338, Approved by FDA

Mfd. for: **Pharmacia & Upjohn Company**
Kalamazoo, MI 49001, USA
By: GlaxoSmithKline
Research Triangle Park, NC 27709

Revised September 2001

**814 055 419
691659**

REFERENCES

- Food and Drug Administration. Freedom of Information Summary: NAXCEL/Ceftiofur Sodium. Available at: www.fda.gov/cvm/efoi/section2/140338s71394.html.
- Jaglan PS, Roof RD, Yein FS, et al. Concentration of ceftiofur metabolites in the plasma and lungs of horses following intramuscular treatment. *J Vet Pharmacol Therap.* 1994;17:24-30.
- Data on file. *Pharmacia Technical Report 795-9760-89-001.*

PHARMACIA Animal Health

www.PharmaciaAH.com

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