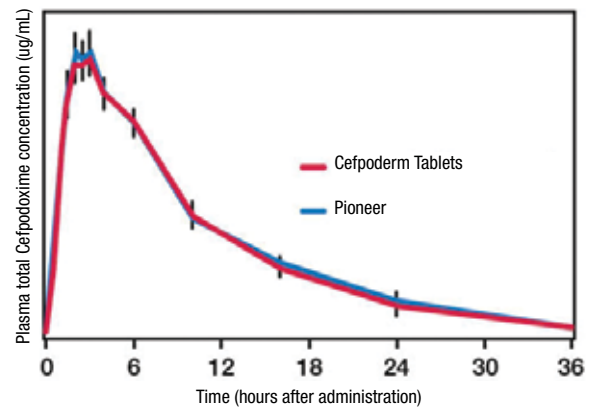




Cefpoderm™ (cefpodoxime proxetil) Tablets



- Cefpoderm Tablets are indicated for the treatment of skin infections (wounds and abscesses) in dogs caused by susceptible strains of *Staphylococcus Pseudintermedius*, *Staphylococcus aureus*, *Streptococcus canis* (group G, β hemolytic), *Escherichia coli*, *Pasteurella multocida*, and *Proteus mirabilis*.
- Bioequivalent to the pioneer drug so you can expect the same safety and efficacy.
- Available as 100 and 200 mg tablets in 100 count bottles.



Bioequivalence data: Cefpoderm Tablets vs. Pioneer



To order, please contact your Dechra or distributor representative or call (866) 683-0660.
For more information, please visit www.dechra-us.com

Important Safety Information: As with all drugs, side effects may occur. Cefpoderm Tablets should not be used in dogs that are hypersensitive to penicillin or cephalosporin. Safety in pregnant and lactating animals or breeding male dogs has not been established. The following adverse reactions have been reported: vomiting, diarrhea, increased thirst and decreased appetite. Refer to the prescribing information for complete details or visit www.dechra-us.com.

24-hour Veterinary Technical Support available (866) 933-2472.
Nonurgent Technical Support available via email support@dechra.com.

Cefpoderm™

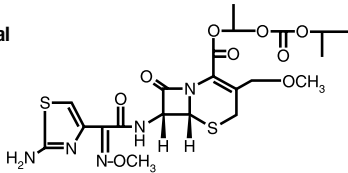
(cefepodime proxetil) Tablets

For Oral Use in Dogs Only

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

DESCRIPTION: Cefepodime proxetil is an orally administered, extended spectrum, semi-synthetic cephalosporin antibiotic. The chemical name is: (+/-)-1-Hydroxyethyl(+)-(6R,7R)-7-[2-(2-amino-4-thiazolyl)glyoxylamido]-3-methoxymethyl)-8-oxo-5-thia-1-azabicyclo[4.2.0]oct-2-ene-2-carboxylate, 7⁻-(Z)-(O-methylxime), isopropyl carbonate (ester) [87239-81-4].

Cefepodime Proxetil Chemical Structure:



Cefepodime proxetil is a prodrug; its active metabolite is cefepodime. All doses of Cefpoderm (cefepodime proxetil) tablets are expressed in terms of the active cefepodime moiety. Cefpoderm is available as: **100 mg Tablet**, each yellow, elliptical, scored tablet contains cefepodime proxetil equivalent to 100 mg of cefepodime. **200 mg Tablet**, each orange, oblong, tablet contains cefepodime proxetil equivalent to 200 mg of cefepodime.

INDICATION: Cefpoderm is indicated for the treatment of skin infections (wounds and abscesses) in dogs caused by susceptible strains of *Staphylococcus pseudintermedius*, *Staphylococcus aureus*, *Streptococcus canis* (group G, β hemolytic), *Escherichia coli*, *Pasteurella multocida*, and *Proteus mirabilis*.

DOSAGE AND ADMINISTRATION: Dose range: The dose range of Cefpoderm (cefepodime proxetil) tablets is 5-10 mg/kg (2.3-4.5 mg/lb) body weight, administered orally, once a day. The dose may be given with or without food. The determination of dosage for any particular patient must take into consideration such factors as the severity and nature of the infection, the susceptibility of the causative organisms, and the integrity of the patient's host-defense mechanisms. Obtain a sample of the pathogenic organism for culture and sensitivity testing prior to beginning antimicrobial therapy. Once results become available, continue with appropriate therapy.

Duration: Cefpoderm tablets should be administered once daily for 5-7 days or for 2-3 days beyond the cessation of clinical signs, up to a maximum of 28 days. Treatment of acute infections should not be continued for more than 3-4 days if no response to therapy is seen.

Dosing Charts: For daily oral administration of Cefpoderm at 5 mg/kg (Table 1) and 10 mg/kg (Table 2).

Table 1. Dose Table for Cefpoderm Tablets at 5 mg/kg Total Daily Dosage

Weight of Dog (lbs)					
Daily Dose	22	44	66	88	132
No. of 100 mg tablets	0.5	1	1.5		1
No. of 200 mg tablets			1	1	
Weight of Dog (kgs)					
Daily Dose	10	20	30	40	60
No. of 100 mg tablets	0.5	1	1.5		1
No. of 200 mg tablets			1	1	

Table 2. Dose Table for Cefpoderm Tablets at 10 mg/kg Total Daily Dosage

Weight of Dog (lbs)						
Daily Dose	11	22	44	66	88	132
No. of 100 mg tablets	0.5	1		1		
No. of 200 mg tablets			1	1	2	3
Weight of Dog (kgs)						
Daily Dose	5	10	20	30	40	60
No. of 100 mg tablets	0.5	1		1		
No. of 200 mg tablets			1	1	2	3

CONTRAINDICATIONS: Cefepodime proxetil is contraindicated in dogs with known allergy to cefepodime or to the β-lactam (penicillins and cephalosporins) group of antibiotics.

WARNINGS: Not for human use. Keep this and all drugs out of reach of children and pets. Antimicrobial drugs, including penicillins and cephalosporins, can cause allergic reactions in sensitized individuals. To minimize the possibility of allergic reactions, those handling such antimicrobials, including cefepodime, are advised to avoid direct contact of the product with the skin and mucous membranes.

PRECAUTIONS: The safety of cefepodime proxetil in dogs used for breeding, pregnant dogs, or lactating bitches has not been demonstrated. As with other cephalosporins, cefepodime proxetil may occasionally induce a positive direct Coombs' test.

ADVERSE REACTIONS: A total of 216 dogs of various breeds and ages ranging from 2 months to 15 years were included in the field study safety analysis. The following table shows the number of dogs displaying each clinical observation.

Table 3. Abnormal Health Findings in the U.S. Field Study¹

Clinical Observation	Cefepodime Proxetil (n=118)	Active Control (n=98)
Vomiting	2	4
Diarrhea	1	1
Increased water drinking	0	2
Decreased appetite	1	1

¹Dogs may have experienced more than one of the observations during the study.

To report suspected adverse events, for technical assistance or to obtain a copy of the safety data sheet (SDS), contact Dechra at (866) 933-2472.

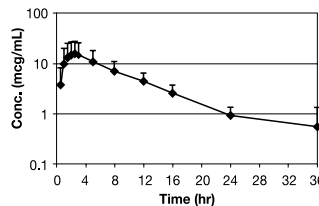
For additional information about adverse drug experience reporting for animal drugs, contact FDA at 1-888-FDA-VEFS, or <http://www.fda.gov/AnimalVeterinary/SafetyHealth>

CLINICAL PHARMACOLOGY: Pharmacokinetics/

Pharmacodynamics: Cefepodime proxetil is a prodrug that is absorbed from and de-esterified in the gastrointestinal tract to its active metabolite, cefepodime. Following oral administration to fasting Beagles, oral bioavailability was 63.1 ± 5.3%.

Figure 1 displays the mean (+ 1SD) plasma cefepodime concentrations and Table 4 lists the mean (SD) pharmacokinetic parameters following administration of cefepodime proxetil tablets to fasting Beagles.

Figure 1. Canine Plasma Concentration of Cefepodime After a Single Oral Dose of 10 mg/kg Cefepodime Proxetil Tablets



Cefepodime is distributed in the body with an apparent volume of distribution of 151 ± 27 mL/kg. Like other β-lactam antibiotics, cefepodime is eliminated from the body primarily in the urine, with an apparent elimination half-life of approximately 5-6 hours after oral administration. This is similar to the 4.7 hour apparent elimination half-life observed after intravenous dosing. Following intravenous administration of 10 mg/kg, the average total body clearance (Cl_b) was 22.7 ± 4.19 mL/hr/kg.

Table 4. Summary of Pharmacokinetic Parameters Obtained after a Single Oral Dose of 10 mg Cefepodime/kg BW, Administered as a Tablet

PK Parameter	Unit	Tablet (SD)
AUC _{0-∞}	mcg-hr/mL	145 (77.6)
AUC ₀₋₁₂₀	mcg-hr/mL	142 (77.5)
Maximum concentration (C _{max})	mcg/mL	16.4 (11.8)
Terminal plasma elimination half-life (t _{1/2β})	hr	5.61 (1.15)
Time of maximum concentration (t _{max})	hr	2.21 (0.542)
Mean residence time (MRT _{0-∞})	hr	9.21 (1.97)

Microbiology: Like other β-lactam antibiotics, cefepodime exerts its inhibitory effect by interfering with bacterial cell wall synthesis. This interference is primarily due to its covalently binding to the penicillin-binding proteins (PBPs) (i.e. transpeptidase and/or carboxypeptidase), which are essential for synthesis of the bacterial cell wall. Therefore, cefepodime is bactericidal. Cefepodime is stable in the presence of many common β-lactamase enzymes. As a result, many organisms resistant to other β-lactam antibiotics (penicillins and some cephalosporins) due to the production of β-lactamases may be susceptible to cefepodime.

Cefepodime has a broad spectrum of clinically useful antibacterial activity that includes staphylococci, streptococci, and Gram-negative species (including *Pasteurella*, *Escherichia*, and *Proteus*). The compound is not active against most obligate anaerobes, *Pseudomonas* spp., or enterococci. The minimum inhibitory concentrations (MICs) for cefepodime against Gram-positive and Gram-negative pathogens isolated from canine skin infections (wounds and abscesses) in a 2002 U.S. field study are presented in Table 5. All MICs were determined in accordance with the Clinical Laboratory Standards Institute (CLSI). Appropriate quality control (QC) ranges for *in vitro* susceptibility testing are presented in Table 6.

TABLE 5. Cefepodime Minimum Inhibitory Concentration Values (mcg/mL) from a 2002 Field Study Evaluating Skin Infections (wounds and abscesses) of Canines in the United States

Organism*	# of Isolates	MIC ₅₀	MIC ₉₀	Range
<i>Staphylococcus pseudintermedius</i>	118	0.12	0.50	0.12->32.0
<i>Streptococcus canis</i> (group G, β hemolytic)	33	≤0.03	≤0.03	≤0.03 [†]
<i>Escherichia coli</i>	41	0.25	0.50	0.12->32.0
<i>Pasteurella multocida</i>	32	≤0.03	≤0.03	≤0.03-0.12
<i>Proteus mirabilis</i>	14	≤0.03	0.06	≤0.03-0.06
<i>Staphylococcus aureus</i>	19	2.0	2.0	0.12-2.0

*No Range, all isolates yielded the same value.

[†]Veterinary specific interpretive criteria have not been established for the above listed canine pathogens by the CLSI at this time.

Table 6. Acceptable Quality Control Ranges for Cefepodime

QC ATCC strain	KB Disk Diffusion Method		Broth Micro-dilution Method
	Drug concentration	Zone diameter	MIC
<i>Escherichia coli</i> 25922	10 mcg	23-28 mm ^a	0.25-1 mcg/mL ^a
<i>Staphylococcus aureus</i> 25923	10 mcg	19-25 mm ^a	
<i>Staphylococcus aureus</i> 29213			1-8 mcg/mL ^a
<i>Staphylococcus pneumoniae</i> 49619	10 mcg	28-34 mm ^a	0.03-0.12 mcg/mL ^b

^a These ranges are for quality control strains used to monitor accuracy of minimum inhibitory concentrations (MICs) of non-fastidious organisms using cation-adjusted Mueller-Hinton agar or broth medium. The dilution range should encompass the QC ranges of these strains in the broth micro-dilution method.

^b These ranges are for quality control strains used to monitor accuracy of minimum inhibitory concentrations (MICs) of fastidious organisms. When susceptibility testing is performed for *Streptococcus canis* (group G, β hemolytic), *Streptococcus pneumoniae* ATCC 49619 should be included as a QC strain in the presence of 5% lysed sheep blood (KB disk diffusion method) or 2.5% lysed horse blood (broth micro-dilution method).

EFFECTIVENESS: The clinical effectiveness of cefepodime proxetil was established in a multi-location (23 site) field study. In this study, 216 dogs with infected wounds or abscesses were treated with either cefepodime proxetil (n=118) once daily at 5 mg/kg (2.3 mg/lb) body weight or with an active control antibiotic (n=98) administered twice daily for 5-7 days. In this study, cefepodime proxetil was considered noninferior to the active control (88.7% versus 88.4% respectively) in the treatment of canine skin infections (wounds and abscesses) caused by susceptible strains of *Staphylococcus pseudintermedius*, *Staphylococcus aureus*, *Streptococcus canis* (group G, β hemolytic), *Escherichia coli*, *Pasteurella multocida*, and *Proteus mirabilis*.

ANIMAL SAFETY: In target animal safety studies, cefepodime was well tolerated at exaggerated daily oral doses of 100 mg/kg/day (10 times the maximum label dose) for 13 weeks in adult dogs and for 28 days in puppies (18-23 days of age). Therefore, once daily administration of cefepodime oral tablets at the maximum labeled dose of 10 mg/kg for up to 28 days was shown to be safe in adult dogs and puppies.

Blood dyscrasia including neutropenias, may be seen following high doses of cephalosporins. Cephalosporin administration should be discontinued in such cases.

STORAGE INFORMATION: Store at controlled room temperature 68-77°F (20-25°C). Replace cap securely after each opening.

HOW SUPPLIED: Cefpoderm (cefepodime proxetil) Tablets are available in the following strengths (cefepodime equivalent), colors, and sizes:

100 mg (yellow, scored, elliptical, debossed with PV on one side, 17 on the other side) Bottles of 100 NDC 17033-431-10
200 mg (orange, oblong, debossed with PV on one side, 18 on the other side) Bottles of 100 NDC 17033-432-10

ANADA 200-543, Approved by FDA

Manufactured by:
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Overland Park, KS 66211 USA

Made in Austria.

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