

CEFPODERM- cefpodoxime proxetil tablet Dechra Veterinary Products

Cefpoderm™ (cefpodoxime proxetil) Tablets

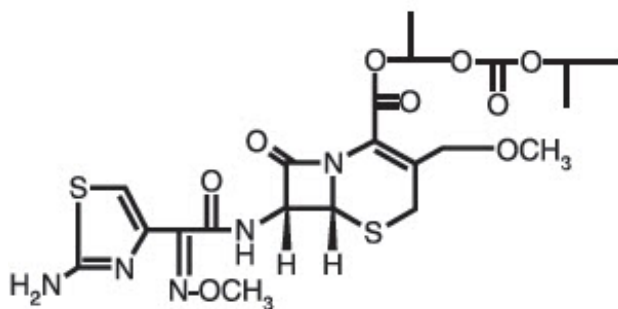
For Oral Use in Dogs Only

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

DESCRIPTION:

Cefpodoxime 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, 7²-(Z)-(0-methyloxime), isopropyl carbonate (ester) [87239-81-4].

Cefpodoxime Proxetil Chemical Structure:



Cefpodoxime proxetil is a prodrug; its active metabolite is cefpodoxime. All doses of Cefpoderm (cefpodoxime proxetil) tablets are expressed in terms of the active cefpodoxime moiety. Cefpoderm is available as:

100 mg Tablet, each yellow, elliptical, scored tablet contains cefpodoxime proxetil equivalent to 100 mg of cefpodoxime.

200 mg Tablet, each orange, oblong, tablet contains cefpodoxime proxetil equivalent to 200 mg of cefpodoxime.

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 (cefpodoxime 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:

Cefpodoxime proxetil is contraindicated in dogs with known allergy to cefpodoxime 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 cefpodoxime, are advised to avoid direct contact of the product with the skin and mucous membranes.

PRECAUTIONS:

The safety of cefpodoxime proxetil in dogs used for breeding, pregnant dogs, or lactating bitches has not been demonstrated. As with other cephalosporins, cefpodoxime 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 Study*

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

* Dogs 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-VETS, or <http://www.fda.gov/AnimalVeterinary/SafetyHealth>

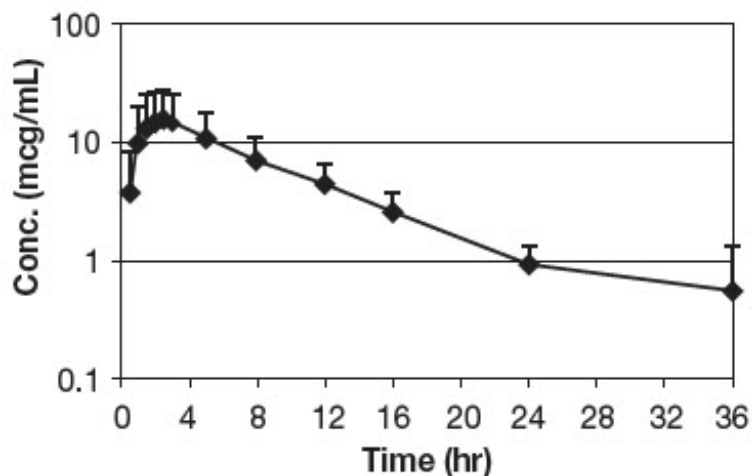
CLINICAL PHARMACOLOGY:

Pharmacokinetics/Pharmacodynamics:

Cefpodoxime proxetil is a prodrug that is absorbed from and de-esterified in the gastrointestinal tract to its active metabolite, cefpodoxime. Following oral administration to fasting Beagles, oral bioavailability was $63.1 \pm 5.3\%$.

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

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



Cefpodoxime is distributed in the body with an apparent volume of distribution of 151 ± 27 mL/kg. Like other β -lactam antibiotics, cefpodoxime 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
Cefpodoxime/kg BW, Administered as a Tablet**

PK Parameter	Unit	Tablet (SD)
AUC _{0-∞}	mcg·hr/mL	145 (77.6)
AUC _{0-LOQ}	mcg·hr/mL	142 (77.5)
Maximum concentration (C _{max})	mcg/mL	16.4 (11.8)
Terminal plasma elimination half-life (t _{1/2,z})	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, cefpodoxime 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, cefpodoxime is bactericidal. Cefpodoxime 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 cefpodoxime.

Cefpodoxime 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 cefpodoxime 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. Cefpodoxime 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

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

† No Range, all isolates yielded the same value.

Table 6. Acceptable Quality Control Ranges for Cefpodoxime

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*	0.25-1 mcg/mL*
<i>Staphylococcus aureus</i> 25923	10 mcg	19-25 mm*	
<i>Staphylococcus aureus</i> 29213			1-8 mcg/mL*
<i>Staphylococcus pneumoniae</i> 49619	10 mcg	28-34 mm†	0.03-0.12 mcg/mL†

* 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.

† 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 cefpodoxime 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 cefpodoxime proxetil (n=118) once daily at 5 mg/kg (2.3 mg/lb) body weight or with a active control antibiotic (n=98) administered twice daily for 5-7 days. In this study, cefpodoxime 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, cefpodoxime 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 cefpodoxime 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 (cefprozime proxetil) Tablets are available in the following strengths (cefprozime 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 with PV on one side, 18 on the other side)

Bottles of 100 NDC 17033-432-10

ANADA 200-543, Approved by FDA

Manufactured for:

Dechra Veterinary Products

7015 College Boulevard, Suite 525

Overland Park, KS 66211 USA

Made in Austria.

Rev. March 2018

PRINCIPAL DISPLAY PANEL - 100 mg Tablet Bottle Label

100 mg

Cefpoderm™

(cefprozime proxetil) Tablets

Antimicrobial For Oral Use

100 mg

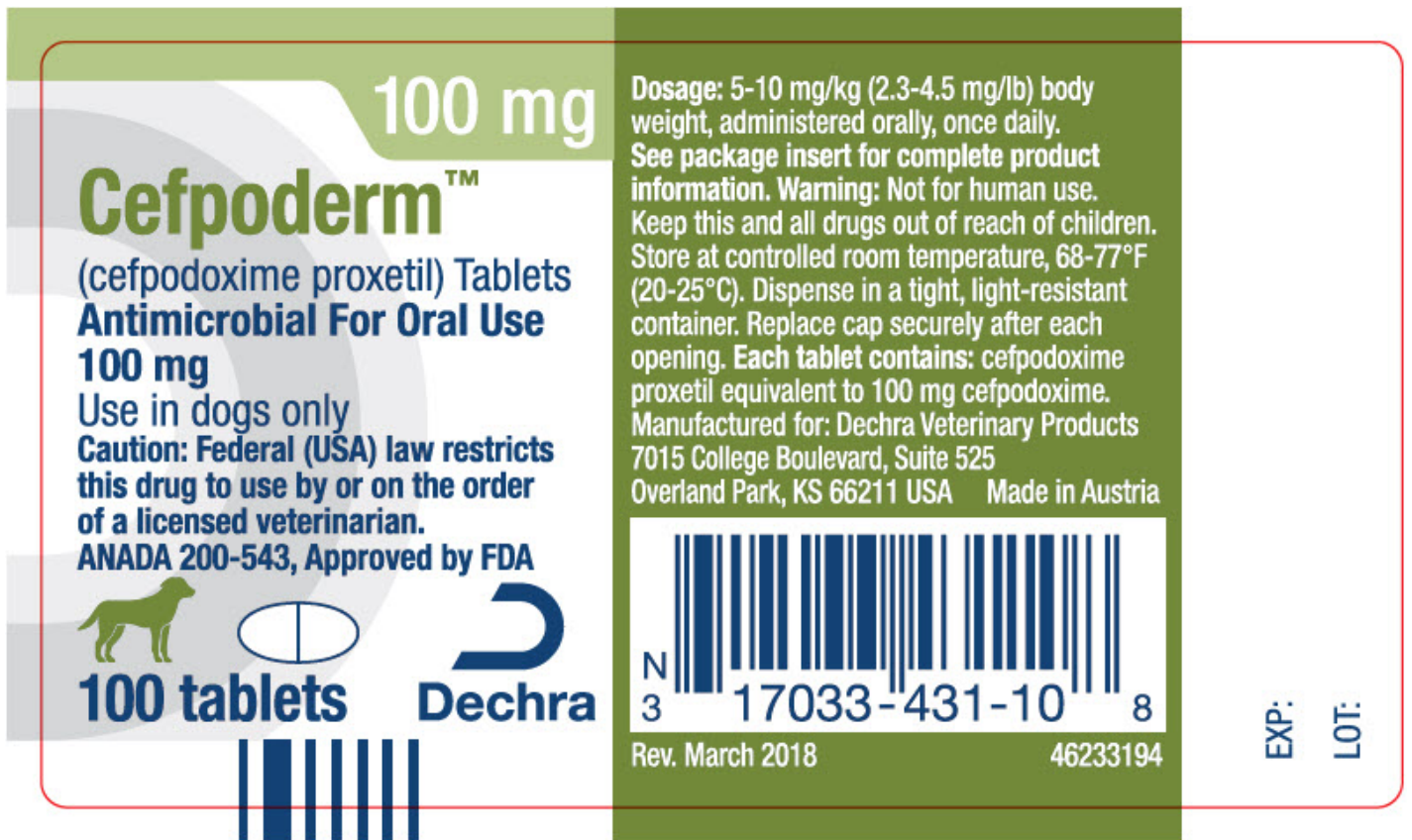
Use in dogs only

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ANADA 200-543, Approved by FDA

100 tablets

Dechra



PRINCIPAL DISPLAY PANEL - 200 mg Tablet Bottle Label

200 mg

Cefpoderm™

(cefpodoxime proxetil) Tablets

Antimicrobial For Oral Use

200 mg

Use in dogs only

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

ANADA 200-543, Approved by FDA

100 tablets

Dechra

200 mg

Cefpoderm™

(cefpodoxime proxetil) Tablets
Antimicrobial For Oral Use

200 mg

Use in dogs only

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

ANADA 200-543, Approved by FDA



100 tablets

Dechra



Dosage: 5-10 mg/kg (2.3-4.5 mg/lb) body weight, administered orally, once daily. See package insert for complete product information. **Warning: Not for human use.** Keep this and all drugs out of reach of children. Store at controlled room temperature, 68-77°F (20-25°C). Dispense in a tight, light-resistant container. Replace cap securely after each opening. Each tablet contains: cefpodoxime proxetil equivalent to 200 mg cefpodoxime. Manufactured for: Dechra Veterinary Products 7015 College Boulevard, Suite 525 Overland Park, KS 66211 USA Made in Austria



Rev. March 2018

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EXP:

LOT:

CEFPODERM

cefpodoxime proxetil tablet

Product Information

Product Type	PRESCRIPTION ANIMAL DRUG	Item Code (Source)	NDC:17033-431
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Cefpodoxime proxetil (UNII: 2TB00A1Z7N) (CEFPODOXIME - UNII:7R4F94TVGY)	CEFPODOXIME	100 mg

Product Characteristics

Color	YELLOW	Score	2 pieces
Shape	OVAL	Size	11mm
Flavor		Imprint Code	PV17
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:17033-431-10	100 in 1 BOTTLE, PLASTIC		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANADA	ANADA200543	12/19/2018	

CEFPODERM

cefepodoxime proxetil tablet

Product Information

Product Type	PRESCRIPTION ANIMAL DRUG	Item Code (Source)	NDC:17033-432
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Cefepodoxime proxetil (UNII: 2TB00A1Z7N) (CEFPODOXIME - UNII:7R4F94TVGY)	CEFPODOXIME	200 mg

Product Characteristics

Color	ORANGE	Score	no score
Shape	OVAL	Size	16 mm
Flavor		Imprint Code	PV18
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:17033-432-10	100 in 1 BOTTLE, PLASTIC		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANADA	ANADA200543	12/19/2018	

Labeler - Dechra Veterinary Products (362142734)

Revised: 1/2019

Dechra Veterinary Products