



convenia[®]
cefovecin sodium

CONFIDENCE IN COMPLIANCE

Pet Owner Confidence

Compliance

Helps your clients navigate their busy schedules by providing a solution, right in your clinic.¹

Visible Assurance

Improvement in clinical signs of infection may be seen within hours after injection.²

Vet Confidence

Compliance

Gives patients an assured course of antibiotic therapy for common bacterial skin infections for up to 14 days with a single injection.^{1,2*}

Proven Efficacy

In a US efficacy study, 86% of dogs needed just 1 injection to resolve their bacterial skin infection.¹

Assured Administration

Eliminates the compliance challenges associated with time dependent antibiotics such as doses given at incorrect intervals or failure to administer all the prescribed doses.

IMPORTANT SAFETY INFORMATION:

People with known hypersensitivity to penicillin or cephalosporins should avoid exposure to Convenia.

Do not use in animals with a history of allergic reactions to penicillins or cephalosporins.

Side effects for both dogs and cats include vomiting, diarrhea, decreased appetite/anorexia and lethargy.

Please see Brief Summary of full Prescribing Information on page 48.

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*In a clinical study, 86% of dogs needed 1 injection to resolve their bacterial skin infection.

ACUTE SUPERFICIAL PYODERMA: LATERAL NECK

Meet Charlie, a 10-year old Golden Retriever treated with Convenia 8 mg/kg for bacterial skin infection contributing to pyotraumatic dermatitis.^{3†}

Baseline



24 hrs. post-injection



72 hrs. post-injection



Photos: David Bird, DVM

Convenia works fast:

- Rapidly absorbed into the bloodstream and then redistributed into the tissues by 30 minutes.²
- Improvement in clinical signs of infection may be seen within hours after injection.²
- Killing bacteria to provide up to 14 days of antibiotic therapy.^{2*}

100% Compliance:

Eliminates the hassle of having to pill the patient and the stress of missed doses.



1

Dose of Convenia*

Up to 14 days of oral antibiotics

References:

* In a clinical study, 86% of dogs needed 1 injection to resolve their bacterial skin infection.

† The only other treatment Charlie received was an initial skin cleansing with a diluted topical antiseptic.

1. Six R, Chemi J, Chesebrough R, et al. Efficacy and safety of cefovecin in treating bacterial folliculitis, abscesses, or infected wounds in dogs. J Am Vet Med. 2008;233(3):433-439 doi:10.2460/javma.233.3.433

2. Stegemann MR, Sherington J, Blanchflower S. Pharmacokinetics and pharmacodynamics of cefovecin in dogs. J Vet Pharmacol Ther. 2006;29(6):501-511. doi:10.1111/j.1365-2885.2006.00801.x

3. ZMR: The Bird's Eye Perspective of Bacterial Skin Disease: Challenging Thoughts to Consider.

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Be ready to talk with your clients about their dogs' hot spots or pyoderma.

State the issue

Ms. Jones, my exam and skin cytology revealed that Charlie has a bacterial skin infection.

Or, for a follow-up visit,

Ms. Jones, my exam revealed a need to modify Charlie's treatment plan for his bacterial skin infection.

State the solution

Convenia provides 100% compliance, an assured course of therapy – without the owner giving an antibiotic by mouth, every day.²

Fast onset and fast relief. Convenia has a fast onset which can give Charlie fast relief because Convenia gets to the site of infection within 30 minutes and starts killing bacteria within hours.^{1,2}

In a clinical study, most dogs needed only 1 injection to resolve their bacterial skin infection.¹

Make your recommendation

Ms. Jones, I believe Convenia is a great choice for Charlie for all the reasons we have discussed: no need for pills, fast relief, and one injection is all most dogs require.^{1,2*} Do you have any questions?

convenia®

(cefovecin sodium)

Antimicrobial for Subcutaneous Injection in Dogs and Cats Only

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

INDICATIONS:

Dogs

CONVENIA is indicated for the treatment of skin infections (secondary superficial pyoderma, abscesses, and wounds) in dogs caused by susceptible strains of *Staphylococcus intermedius* and *Streptococcus canis* (Group G).

Cats

CONVENIA is indicated for the treatment of skin infections (wounds and abscesses) in cats caused by susceptible strains of *Pasteurella multocida*.

DOSAGE AND ADMINISTRATION:

Dogs

CONVENIA should be administered as a single subcutaneous injection of 3.6 mg/lb (8 mg/kg) body weight. A second subcutaneous injection of 3.6 mg/lb (8 mg/kg) may be administered if response to therapy is not complete. The decision for a second injection for any individual dog should take into consideration such factors as progress toward clinical resolution, the susceptibility of the causative organisms, and the integrity of the dog's host-defense mechanisms. Therapeutic drug concentrations after the first injection are maintained for 7 days for *S. intermedius* infections and for 14 days for *S. canis* (Group G) infections. Maximum treatment should not exceed 2 injections.

Cats

CONVENIA should be administered as a single, one-time subcutaneous injection at a dose of 3.6 mg/lb (8 mg/kg) body weight. After an injection of CONVENIA, therapeutic concentrations are maintained for approximately 7 days for *Pasteurella multocida* infections.

General Dosing Information

A sample of the lesion should be obtained for culture and susceptibility testing prior to beginning antimicrobial therapy. Once results become available, continue with appropriate therapy. If acceptable response to treatment is not observed, or if no improvement is seen within 3 to 4 days, then the diagnosis should be re-evaluated and appropriate alternative therapy considered.

CONVENIA may persist in the body for up to 65 days. The effect of remaining concentrations of cefovecin on any subsequent antimicrobial therapies has not been determined. Fluoroquinolone and aminoglycoside antimicrobials have been reported to be compatible with cephalosporin antimicrobial agents.^{1,2,3}

Table 1: Dose Table for CONVENIA at 8 mg/kg Body Weight

Weight of Animal	Volume of CONVENIA (3.6 mg/lb or 0.045 mL/lb)
5 lb	0.23 mL
10 lb	0.45 mL
15 lb	0.67 mL
20 lb	0.90 mL
40 lb	1.8 mL
80 lb	3.6 mL

PREPARATION OF SOLUTION FOR INJECTION: To deliver the appropriate dose, aseptically reconstitute CONVENIA with 10 mL Sterile Water for Injection. Shake and allow vial to sit until all material is visually dissolved. The resulting solution contains cefovecin sodium equivalent to 80 mg/mL cefovecin. CONVENIA is light sensitive. The vial should be stored in the original carton and refrigerated when not in use. Use the entire contents of the vial within 56 days of reconstitution.

CONTRAINDICATIONS: CONVENIA is contraindicated in dogs and cats with known allergy to cefovecin or to β -lactam (penicillins and cephalosporins) group antimicrobials. Anaphylaxis has been reported with the use of this product in foreign market experience. If an allergic reaction or anaphylaxis occurs, CONVENIA should not be administered again and appropriate therapy should be instituted. Anaphylaxis may require treatment with epinephrine and other emergency measures, including oxygen, intravenous fluids, intravenous antihistamine, corticosteroids, and airway management, as clinically indicated. Adverse reactions may require prolonged treatment due to the prolonged systemic drug clearance (65 days).

WARNINGS: Not for use in humans. Keep this and all drugs out of reach of children. Consult a physician in case of accidental human exposure. For subcutaneous use in dogs and cats only. 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 cefovecin, are advised to avoid direct contact of the product with the skin and mucous membranes.

PRECAUTIONS: Prescribing antibacterial drugs in the absence of a proven or strongly suspected bacterial infection is unlikely to provide benefit to treated animals and may increase the risk of the development of drug-resistant animal pathogens.

The safe use of CONVENIA in dogs or cats less than 4 months of age (see **Animal Safety**) and in breeding or lactating animals has not been determined. Safety has not been established for IM or IV administration. The long-term effects on injection sites have not been determined. CONVENIA is slowly eliminated from the body, approximately 65 days is needed to eliminate 97% of the administered dose from the body. Animals experiencing an adverse reaction may need to be monitored for this duration.

CONVENIA has been shown in an experimental *in vitro* system to result in an increase in free concentrations of carprofen, furosemide, doxycycline and ketoconazole. Concurrent use of these or other drugs that have a high degree of protein-binding (e.g. NSAIDs, propofol, cardiac, anticonvulsant, and behavioral medications) may compete with cefovecin binding and cause adverse reactions.

Positive direct Coombs' test results and false positive reactions for glucose in the urine have been reported during treatment with some cephalosporin antimicrobials. Cephalosporin antimicrobials may also cause falsely elevated urine protein determinations. Some antimicrobials, including cephalosporins, can cause lowered albumin values due to interference with certain testing methods.

Occasionally, cephalosporins and NSAIDs have been associated with myelotoxicity, thereby creating a toxic neutropenia⁴. Other hematological reactions seen with cephalosporins include neutropenia, anemia, hypoproteobinemia, thrombocytopenia, prolonged prothrombin time (PT) and partial thromboplastin time (PTT), platelet dysfunction and transient increases in serum aminotransferases.

ADVERSE REACTIONS:

Dogs

A total of 320 dogs, ranging in age from 8 weeks to 19 years, were included in a field study safety analysis. Adverse reactions reported in dogs treated with CONVENIA and the active control are summarized in Table 2.

Table 2: Number of Dogs* with Adverse Reactions Reported During the Field Study with CONVENIA

Adverse Reaction	CONVENIA (n=157)	Active Control (n=163)
Lethargy	2	7
Anorexia/Decreased Appetite	5	8
Vomiting	6	12
Diarrhea	6	7
Blood in Feces	1	2
Dehydration	0	1
Flatulence	1	0
Increased Borborygmi	1	0

*Some dogs may have experienced more than one adverse reaction or more than one occurrence of the same adverse reaction during the study.

Mild to moderate elevations in serum gamma glutamyl transferase or serum alanine aminotransferase were noted post-treatment in several of the CONVENIA-treated dogs. No clinical abnormalities were noted with these findings. One CONVENIA-treated dog in a separate field study experienced diarrhea post-treatment lasting four weeks. The diarrhea resolved.

Cats

A total of 291 cats, ranging in age from 2.4 months (one cat) to 21 years, were included in the field study safety analysis. Adverse reactions reported in cats treated with CONVENIA and the active control are summarized in Table 3.

Table 3: Number of Cats* with Adverse Reactions Reported During the Field Study with CONVENIA.

Adverse Reaction	CONVENIA (n=147)	Active Control (n=144)
Vomiting	10	14
Diarrhea	7	26
Anorexia/Decreased Appetite	6	6
Lethargy	6	6
Hyper/Acting Strange	1	1
Inappropriate Urination	1	0

*Some cats may have experienced more than one adverse reaction or more than one occurrence of the same adverse reaction during the study.

Four CONVENIA cases had mildly elevated post-study ALT (one case was elevated pre-study). No clinical abnormalities were noted with these findings.

Twenty-four CONVENIA cases had normal pre-study BUN values and elevated post-study BUN values (37 – 39 mg/dL post-study). There were 6 CONVENIA cases with normal pre- and mildly to moderately elevated post-study creatinine values. Two of these cases also had an elevated post-study BUN. No clinical abnormalities were noted with these findings.

One CONVENIA-treated cat in a separate field study experienced diarrhea post-treatment lasting 42 days. The diarrhea resolved.

FOREIGN MARKET EXPERIENCE: The following adverse events were reported voluntarily during post-approval use of the product in dogs and cats in foreign markets: death, tremors/ataxia, seizures, anaphylaxis, acute pulmonary edema, facial edema, injection site reactions (alopecia, scabs, necrosis, and erythema), hemolytic anemia, salivation, pruritus, lethargy, vomiting, diarrhea, and inappetence.

CONTACT INFORMATION:

For a copy of the Safety Data Sheet or to report adverse reactions, call Zoetis Inc. at 1-888-963-8471. For additional information about adverse drug experience reporting for animal drugs, contact FDA at 1-888-FDA-VETS or at www.fda.gov/reportanimalae.

ANIMAL SAFETY:

Dogs

CONVENIA administered to healthy four month old dogs at doses of 12 mg/kg (1.5 X), 36 mg/kg (4.5 X), and 60 mg/kg (7.5 X) every seven days by dorsoscapular subcutaneous injections was well-tolerated for a total of 5 doses. Vomiting and diarrhea were seen in all treatment groups, with the incidence of vomiting and the incidence and duration of diarrhea increasing in a dose-related manner. Injection site irritation and transient edema occurred with increasing frequency in a dose-related manner and with repeat injections. Two injection site reactions included a seroma over the shoulder and swelling lasting > 30 days. Dogs dosed at 36 mg/kg had a significant (p = 0.0088) increase in BUN (all means remained within the normal range) compared to the controls. One dog dosed at 60 mg/kg exhibited a glomerulopathy on histopathology, and one dog in this same group had minimal peliosis hepatis.

At an exaggerated dose of 180 mg/kg (22.5X) in dogs, CONVENIA caused some injection site irritation, vocalization and edema. Edema resolved within 8-24 hours.

Cats

CONVENIA administered to healthy four month old cats at doses of 12 mg/kg (1.5 X), 36 mg/kg (4.5 X), and 60 mg/kg (7.5 X) every seven days by dorsoscapular subcutaneous injections was well tolerated for a total of 5 doses. Vomiting and diarrhea were observed in cats, with the incidence of vomiting, and the incidence and duration of diarrhea increasing in a dose-related manner. The mean albumin values for all the CONVENIA-treated cats were significantly lower (p ≤ 0.05) than the control values (all means remained within the normal range) for all time periods. The mean alkaline phosphatase values in the 60 mg/kg group were significantly higher (p ≤ 0.0291) than the control values for all time periods. Injection-site irritation and transient edema occurred with increasing frequency in a dose-related manner and with repeat injections. One cat in the 12 mg/kg group had a mild renal tubular and interstitial fibrosis, and one cat in the 12 mg/kg group had mild glomerulosclerosis on histopathology.

At an exaggerated dose of 180 mg/kg (22.5X), CONVENIA was associated with injection site irritation, vocalization and edema. Edema resolved within 8-24 hours. On Day 10, cats had lower mean white blood cell counts compared to the controls. One cat had a small amount of bilirubinuria on Day 10.

STORAGE INFORMATION:

Store the powder and the reconstituted product in the original carton, refrigerated at 2° to 8° C (36° to 46° F). **Use the entire contents of the vial within 56 days of reconstitution.** PROTECT FROM LIGHT. After each use it is important to return the unused portion back to the refrigerator in the original carton. As with other cephalosporins, the color of the solution may vary from clear to amber at reconstitution and may darken over time. If stored as recommended, solution color does not adversely affect potency.

HOW SUPPLIED:

CONVENIA is available as a 10 mL multi-use vial containing 800 milligrams of cefovecin as a lyophilized cake.

REFERENCES:

- ¹Pillai SK, Moellering RC, and Eliopoulos GM. 2005. Antimicrobial combinations, pp 365-440. In V. Lorian (ed.) *Antibiotics in Laboratory Medicine*, 5th ed., Lippincott, Williams, and Wilkins, Philadelphia, PA.
- ²Fish DN, Choi MK, and Jung R. Synergic activity of cephalosporins plus fluoroquinolones against *Pseudomonas aeruginosa* with resistance to one or both drugs. *Journal of Antimicrobial Chemotherapy* (2002) 50, 1045-1049.
- ³Mayer I and Nagy E. Investigation of the synergic effects of aminoglycoside-fluoroquinolone and third-generation cephalosporin combinations against clinical isolates of *Pseudomonas* spp. *Journal of Antimicrobial Chemotherapy* (1999) 43, 651-657.
- ⁴Richard SJ and Sherding RG. *Saunders Manual of Small Animal Practice*, 2nd edition. W.B. Saunders Co. 2000: p. 166.

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