

Brief Summary of Prescribing Information

convenia®

(cefovecin sodium)

Antimicrobial for Subcutaneous Injection in Dogs and Cats Only

CAUTION: Federal (USA) 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*.

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 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 neutropenia¹. Other hematological reactions seen with cephalosporins include neutropenia, anemia, hypoprothrombinemia, 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 γ -glutamyl trans-ferase 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 4 weeks. The diarrhea resolved.

Cats

A total of 291 cats, ranging in age from 2.4 months (1 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=157)	Active Control (n=163)
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 (1 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.

For a copy of the Material Safety Data Sheet, (MSDS) or to report a suspected adverse reaction call Zoetis Inc. at 1-888-963-8471.

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.

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zoetis

Distributed by
Zoetis Inc.
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Practicing “Toothanasia”



WSAVA
Global Veterinary Community

Feline stomatitis prevalence estimates range from 0.7% to 12%, but no direct causes have

been proven. Medical management provides palliative relief, but long-term control is rare. This case series evaluated outcome of tooth extraction in 95 cats with stomatitis. Extraction of all stomatitis-affected and otherwise diseased teeth resulted in either full-mouth extraction (FME, $n = 60$) or partial-mouth extraction (PME, $n = 35$). Median follow-up time was 231 days. Patients were given effectiveness of treatment (EOT) scores based on clinical sign improvement and need for extended medical management (EMM). More than two-thirds of cats (64/95) showed either substantial clinical improvement or complete resolution of stomatitis, although 44 required EMM (antimicrobial, antiinflammatory, or analgesic) for a finite period. There was no significant difference in EOT between cats treated with PME vs FME. Treatment with antimicrobials, antiinflammatories, or analgesics prior to FME or PME was not associated with EOT scores. Likewise, clinical sign duration had no bearing on overall EOT scores. Cats showing a positive response by their first follow-up visit were more likely to have more positive long-term results. Results support PME if not all teeth exhibit stomatitic lesions, but clients must be educated about the disease's chronic nature and likely need for EMM.

Global Commentary

Extraction is recognized as an effective treatment for caudal stomatitis; however, its irreversibility worries many pet owners. Steve Holmstrom called extraction “toothanasia” and Colin Harvey “a dentist's admission of defeat.” Reasonable use of extractions should be a goal for veterinarians and veterinary dentists.

This study provides information for reasonable algorithms in caudal stomatitis management. The results highlight extraction as a logical, effective modality of definitive treatment. An important study detail was that the standard of treatment included not only surgery but also criteria for case selection, pain management, and follow-up.

Many of the cats (even edentulous) required further medical treatment. This is because plaque remains an important causative factor of caudal stomatitis and will accumulate on a cat's tongue and mucosal surfaces. If plaque is not controlled, glossectomy is certainly not a treatment option, but there are still other conservative methods available: cyclosporine, steroids, or recombinant interferon omega.—*Jerzy Gawor, DVM, PhD, FAVD, DAVDC*

Source

Jennings MW, Lewis JR, Soltero-Rivera MM, Brown DC, Reiter AM. Effect of tooth extraction on stomatitis in cats: 95 cases (2000-2013). *JAVMA*. 2015;246(6):654-660.

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