



PANOQUELL[®]-CA1 (fuzapladib sodium for injection)

The **only** FDA conditionally approved **innovative solution** for the management of clinical signs associated with acute onset of pancreatitis in dogs

User Safety Warnings: Not for use in humans. Keep this medication out of reach of children. Limited data is available on the potential teratogenic effects of fuzapladib.

In case of accidental self-injection, skin contact, eye exposure, or accidental ingestion refer to the package insert.

To obtain a Safety Data Sheet, report suspected adverse drug experiences, or for technical assistance, contact Ceva Animal Health at 1-800-999-0297.

For additional information about reporting adverse drug experiences for animal drugs, contact FDA at 1-888-FDA-VETS or at www.fda.gov/reportanimalae.

 **PANOQUELL[®]-CA1**
(fuzapladib sodium for injection)

14 mg fuzapladib sodium per vial
4 mg/mL when reconstituted

For intravenous use in dogs only.
Reconstitute before using.

PANOQUELL[®]-CA1 is a leukocyte function-associated antigen 1 (LFA-1) activation inhibitor.

Indication: For the management of clinical signs associated with acute onset of pancreatitis in dogs.

Conditionally approved by FDA pending a full demonstration of effectiveness under application number 141-567. It is a violation of Federal law to use this product other than as directed in the labeling.

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



PANOQUELL[®] is a registered trademark of Ishihara Sangyo Kaisha, Ltd.

PAN-100-24v4

Commonly seen by veterinarians, the clinical signs associated with the acute onset of canine pancreatitis can be non-specific.¹

Cases will vary in presentation and severity.¹

How often do you see the clinical signs associated with acute onset of canine pancreatitis?



DEHYDRATION



VOMITING



CRANIAL
ABDOMINAL PAIN



DECREASED
APPETITE



DECREASED
ACTIVITY



DIARRHEA AND/OR
FECAL BLOOD

Pancreatitis HURTS

Safety²

In the pilot field effectiveness study, PANOQUELL®-CA1 was administered safely with other supportive care treatments.

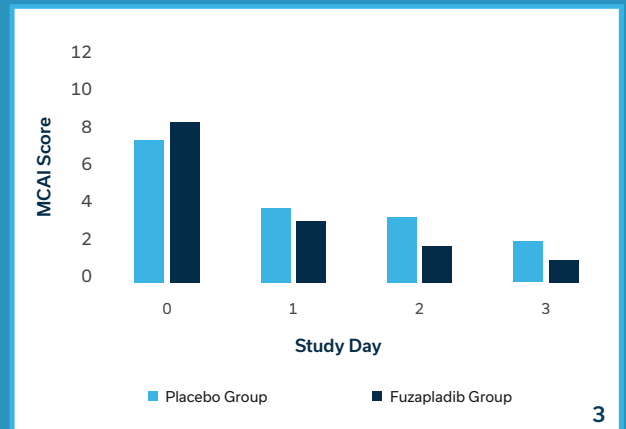
- Supportive care included anti-emetics and pain control.
- The most common adverse reactions included anorexia, digestive tract disorders, respiratory tract disorders, hepatopathy and jaundice.²



Effectiveness^{2,3}

Dogs treated with fuzapladib sodium had a statistically significant reduction in MCAI scores compared to control (p=0.0193).²

A Modified Canine Activity Index (MCAI) was used to evaluate and score seven clinical signs relevant in dogs with acute pancreatitis: Activity, Appetite (voluntary food intake), Vomiting, Cranial abdominal pain, Dehydration, Stool consistency, and Blood in the stool. The primary effectiveness variable was the change in the group mean total MCAI score from Day 0 (pre-treatment) to Day 3, as assessed by the Investigator. Day 0 mean MCAI scores for the fuzapladib sodium and vehicle control groups were 8.53 and 7.68, respectively. The changes in the mean total MCAI scores from Day 0 to 3 for the fuzapladib sodium and vehicle control groups were -7.7 and -5.7, respectively.



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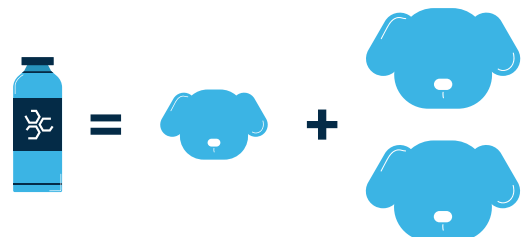
Cost Effective

PANOQUELL®-CA1 comes in a multi-dose vial.



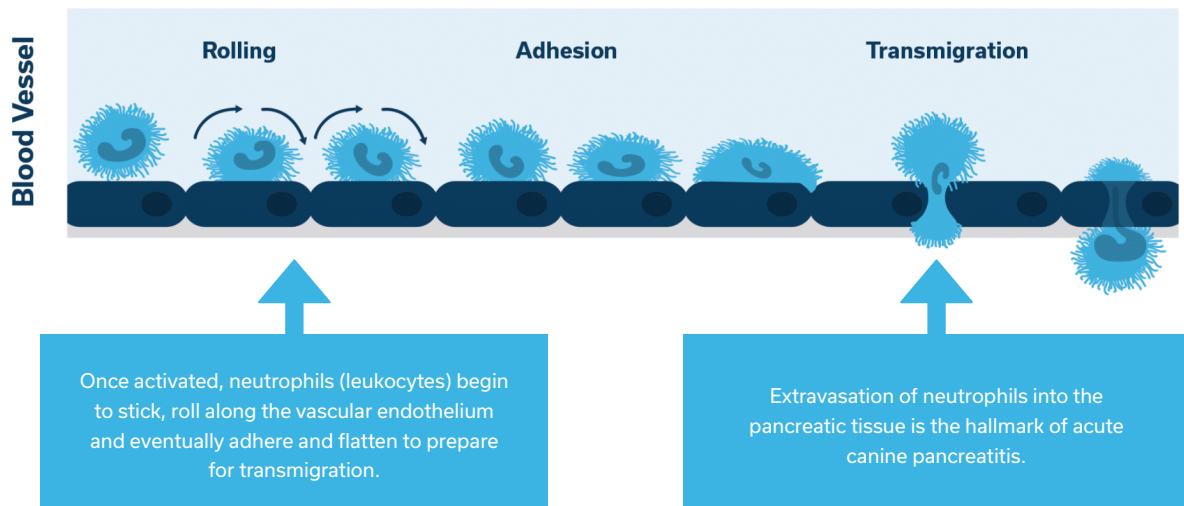
Scan the QR code to see our pricing guide.

One vial will treat one 5 lb dog and two 10 lb dogs for 3 days.



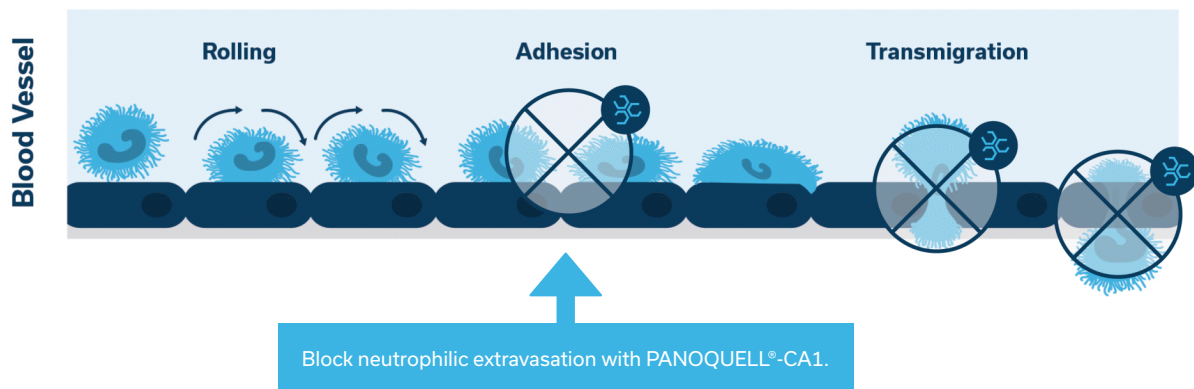
PANOQUELL®-CA1 (fuzapladib sodium for injection) works by inhibiting the activation of LFA-1:²

- Neutrophilic extravasation is the hallmark of acute canine pancreatitis.⁴
- LFA-1 (leukocyte function-associated antigen-1) activation is a critical component of neutrophilic extravasation.⁵



UNIQUE mechanism of action controls inflammation:

- PANOQUELL®-CA1 is an LFA-1 activation inhibitor.



Anti-inflammatory effects through LFA-1 inhibition.

May LIMIT pancreatic lesion expansion and prevent complications such as MULTI-ORGAN FAILURE.²

PANOQUELL[®]-CA1 (fuzapladib sodium for injection)



Visit our website at panoquell.com
or scan the QR code!

IMPORTANT SAFETY INFORMATION: The safe use of PANOQUELL[®]-CA1 has not been evaluated in dogs with cardiac disease, hepatic failure, renal impairment, dogs that are pregnant, lactating, intended for breeding or puppies under 6 months of age. PANOQUELL[®]-CA1 should not be used in dogs with a known hypersensitivity to fuzapladib sodium. PANOQUELL[®]-CA1 is a highly protein bound drug and its use with other highly protein bound medications have not been studied. The most common side effects in the pilot field study were anorexia, digestive tract disorders, respiratory tract disorders and jaundice. PANOQUELL[®]-CA1 is not for use in humans. Limited data is available on the potential teratogenic effects of fuzapladib sodium. Therefore, anyone who is pregnant, breast feeding or planning to become pregnant should avoid direct contact with PANOQUELL[®]-CA1. For additional information on the use of PANOQUELL[®]-CA1, please refer to the product insert.

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Based on the data submitted by the sponsor for the conditional approval of PANOQUELL[®]-CA1, FDA determined that the drug is safe and has a reasonable expectation of effectiveness when used according to the labeling.

What does FDA Conditional Approval Mean? Conditional approval may be granted for a veterinary drug when it is shown to be safe and when used according to the label. In addition, the drug must also demonstrate a “reasonable expectation of effectiveness,” but has not yet been proven to meet the “substantial evidence” standard of effectiveness required for full approval. Conditionally approved drugs may not be used for any off-label indications.

¹ Cridge H, Scott N, Steiner JM. Risk Factors and Clinical Presentation in Dogs with Increased Serum Pancreatic Lipase Concentrations-A Descriptive Analysis. *Animals (Basel)*. 2022 Jun 19;12(12):1581. doi: 10.3390/ani12121581. PMID: 35739917; PMCID: PMC9219463.

² <https://animaldrugsatfda.fda.gov/adafda/app/search/public/document/downloadFoi/13134>

³ Steiner JM, Lainesse C, Noshiro Y, et al. Fuzapladib in a randomized controlled multicenter masked study in dogs with presumptive acute onset pancreatitis. *J Vet Intern Med*. 2023; 37(6): 2084-2092. doi:10.1111/jvim.16897

⁴ Cridge H, Lim SY, Algül H, Steiner JM. New insights into the etiology, risk factors, and pathogenesis of pancreatitis in dogs: Potential impacts on clinical practice. *J Vet Intern Med*. 2022 May;36(3):847-864. doi: 10.1111/jvim.16437. Epub 2022 May 12. PMID: 35546513; PMCID: PMC9151489.

⁵ Margraf A, Lowell CA, Zarbock A. Neutrophils in acute inflammation: current concepts and translational implications. *Blood*. 2022 Apr 7;139(14):2130-2144. doi: 10.1182/blood.2021012295. PMID: 34624098; PMCID: PMC9728535.