KBroVet®-CA1 (potassium bromide chewable tablets)

Reasonable Expectation of Effectiveness – Pilot Study

KBroVet®-CA1 has received conditional approval based on the results of a retrospective study demonstrating reasonable expectation of effectiveness. A retrospective study of 51 dogs was performed to evaluate the safety and efficacy of KBr for the treatment of idiopathic epilepsy in dogs. *(Data on file)*

Determination of Success

The following variables were used to compare the 30-day period before initial treatment with KBr and the 30-day period of steady state KBr dosing. These criteria were necessary to classify an individual case as a success:

- Seizure counts – decrease of ≥ 50%
- Seizure event days per month – decrease of ≥ 50%
- Seizure severity scores – decrease or no change.

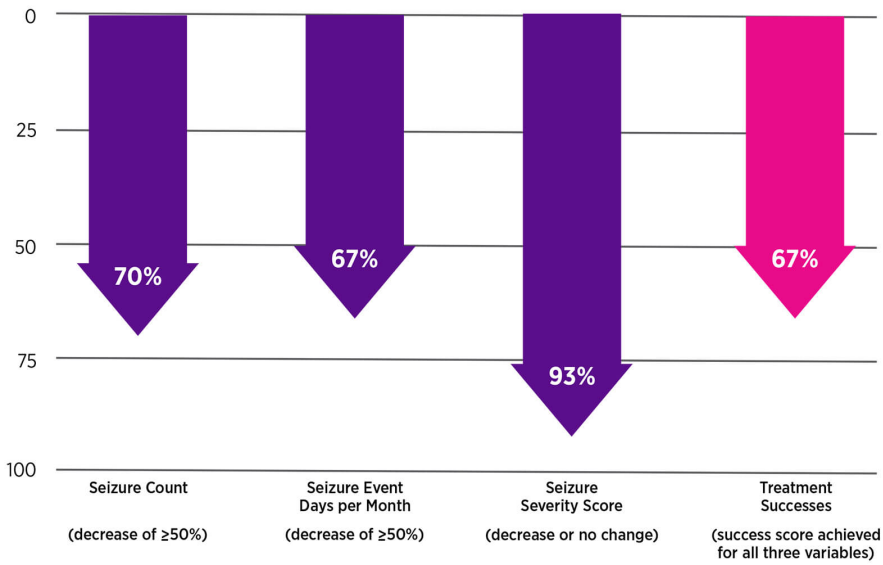
Overall reasonable expectation of effectiveness was achieved if > 50% of all cases achieved a "success" score for **all three variables**.

Results

Effectiveness

Based on study protocol-specified criteria, 27 of the initial 51 cases were determined to be valid for effectiveness data. As the sole antiepileptic, potassium bromide achieved 67% overall treatment success in all three categories.

- **Seizure counts:** 70% (19/27) were defined as treatment successes.
- **Seizure event days per month:** 67% (18/27) were defined as successes by either decreasing or showing no change.
- **Seizure severity scores:** 93% (25/27) were defined as successes by either decreasing or showing no change.
- **Overall, 67% (18/27) treatment successes.**



Safety

In a retrospective field study of 51 dogs diagnosed with idiopathic epilepsy clinical findings of dogs treated with KBr were documented for the initial 60 days of treatment. The most common clinical abnormalities documented in the 60-day period following the initiation of KBr therapy included increased appetite, weight gain, vomiting/regurgitation, sedation and neurologic signs.

Practitioners should tailor therapeutic regimens and clinical monitoring to each dog. Availability of an appropriately FDA-labeled, approved KBr product could provide better assurance to veterinarians and their clients of the quality, safety, and effectiveness of a product for veterinary use.

KBroVet®-CA1 Product Facts

KBroVet-CA1 is the only FDA conditionally approved drug for seizure control in dogs.	Provides better assurance to veterinarians and their clients as a reliable and trusted product, manufactured specifically for dogs, with a two-year shelf life.
KBroVet-CA1 is excreted through glomerular filtration.	An ideal choice for dogs with compromised liver function that cannot tolerate antiepileptics that affect the liver.
KBroVet-CA1 is a liver-flavored, chewable tablet administered once a day and is formulated specifically for dogs.	May improve compliance by providing convenient once a day dosing for owners that cannot dose their dog multiple times each day.
KBroVet-CA1 has a half-life of at least 21 days,[1] the longest half-life of all seizure antiepileptic options.	If owners miss a dose, fluctuation in drug concentration is unlikely to occur, minimizing the occurrence of a seizure.
KBroVet-CA1 is available in 60 and 180 count bottles.	Variety of bottle-count sizes provides more flexibility when dispensing.

[1]Boothe, D, Dewey C, Carpenter D. Comparison of phenobarbital with bromide as a first-choice antiepileptic drug for treatment of epilepsy in dogs. JAVMA. 2012; Vol 240, No 9. 1073-1083.

Dosage & Administration

The total recommended daily dosage range for oral administration is 25–68 mg/kg (11–31 mg/lb) of body weight. The dosage of KBroVet®-CA1 should be adjusted based on monitoring of clinical response of the individual patient. KBroVet®-CA1 may be dosed with or without food.[2] Use of an initial loading dosage regimen may be considered on an individual patient basis, balancing the time required to achieve a therapeutic response while minimizing side effects.

[2]Podell M, Fenner WR. Bromide therapy in refractory canine epilepsy. *J Vet Intern Med.* 1993; 7(5): 318-27.

Precautions

Dogs receiving KBr should be carefully monitored when changing diets, administering chloride-containing intravenous fluids, and administering concurrent medications. Careful monitoring is important in dogs that have a condition that may cause difficulty maintaining electrolyte balance.

- Animals with decreased renal function may be predisposed to bromide toxicosis.
- Some dogs may experience epileptic episodes that are unresponsive or refractory to KBr monotherapy and KBr alone may not be adequate for control of seizures for every dog with idiopathic epilepsy.
- The safe use of KBroVet®-CA1 has not been evaluated in dogs that are intended for breeding, or that are pregnant or lactating. The safe use of KBr in neonates and young animals has not been established.
- Reproductive effects of KBr have been reported in other species.
- In dogs, ataxia, diarrhea, hematochezia, excessive salivation, shivering, skin lesions, stupor progressing to coma, and death have been reported.

IMPORTANT SAFETY INFORMATION:

KBroVet®-CA1 is conditionally approved by FDA pending a full demonstration of effectiveness under application number 141-544. See prescribing information for complete details regarding adverse events, warnings, and precautions. It is a violation of Federal Law to use this product other than as directed in the labeling. Contraindicated in dogs with a history of hypersensitivity to bromide. Not for use in cats. Not for human use. Keep out of reach of children. Contact a physician in case of accidental ingestion by humans. The most commonly reported side effects were increased appetite and thirst, increased urination, weight gain, sedation, and ataxia. Reversible neurologic signs (sedation, ataxia, weakness) were generally associated with adjunctive potassium bromide treatment or high serum bromide concentrations. Animals with kidney disease may be predisposed to bromide toxicities. The safe use of KBroVet®-CA1 has not been evaluated in dogs that are intended for breeding, are pregnant or lactating, or less than 6 months of age. Use caution with when changing diets, administering chloride-containing IV fluids, and administering concurrent medications. Careful monitoring is important in dogs that have a condition that may cause difficulty maintaining electrolyte balance.