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PRN® PHARMACAL

But idiopathic epilepsy in dogs can be safely and reliably controlled.

For a pet owner, witnessing their dog experiencing a seizure can be a traumatic experience, leaving them overwhelmed by a sense of helplessness and fear. A diagnosis of idiopathic epilepsy can feel like a dark cloud always hanging around … a persistent lingering anxiety as they wait for the next seizure episode to strike.

What is Idiopathic Epilepsy?

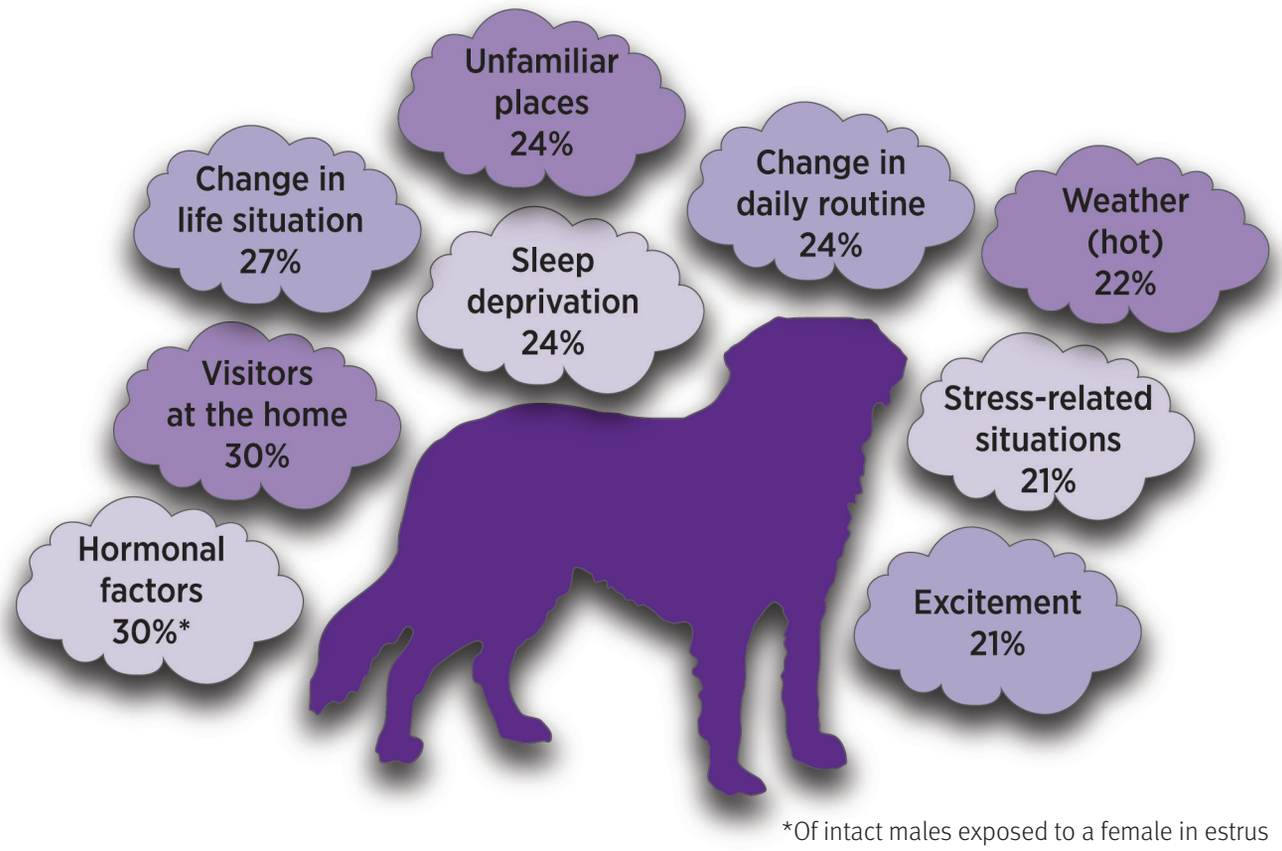
Idiopathic epilepsy (IE), recurrent seizures with no identifiable structural or biochemical cause, is the **most common chronic neurologic disorder in dogs**.[1,2] Epileptic seizures are transient signs caused by abnormal excessive or synchronous neuronal activity in the brain.[3,4] The frequency, type and severity of seizures can vary tremendously, ranging from several a day (status epilepticus) to less than one a year.

Facts & Figures

- **Risk Factors:** Poorly defined, but literature supports an underlying genetic component with a higher prevalence in purebred dogs compared with mixed breed dogs.[3]
- **Prevalence:** Estimated to be between 0.5% and 6% of the canine population.[3] That means there are approximately 2.1 million epileptic dogs in the United States.[4]
- **Age predilection:** Most dogs with idiopathic epilepsy experience their first seizure between 6 months and 6 years of age.[3, 5]

Precipitating Factors

In an observational study, the owners of 50 dogs diagnosed with idiopathic epilepsy were interviewed using a predefined questionnaire regarding possible seizure-precipitating factors.[6] Of the 50 dogs, 74% (37) had at least one seizure-precipitating factor.



*Of intact males exposed to a female in estrus

Diagnosis

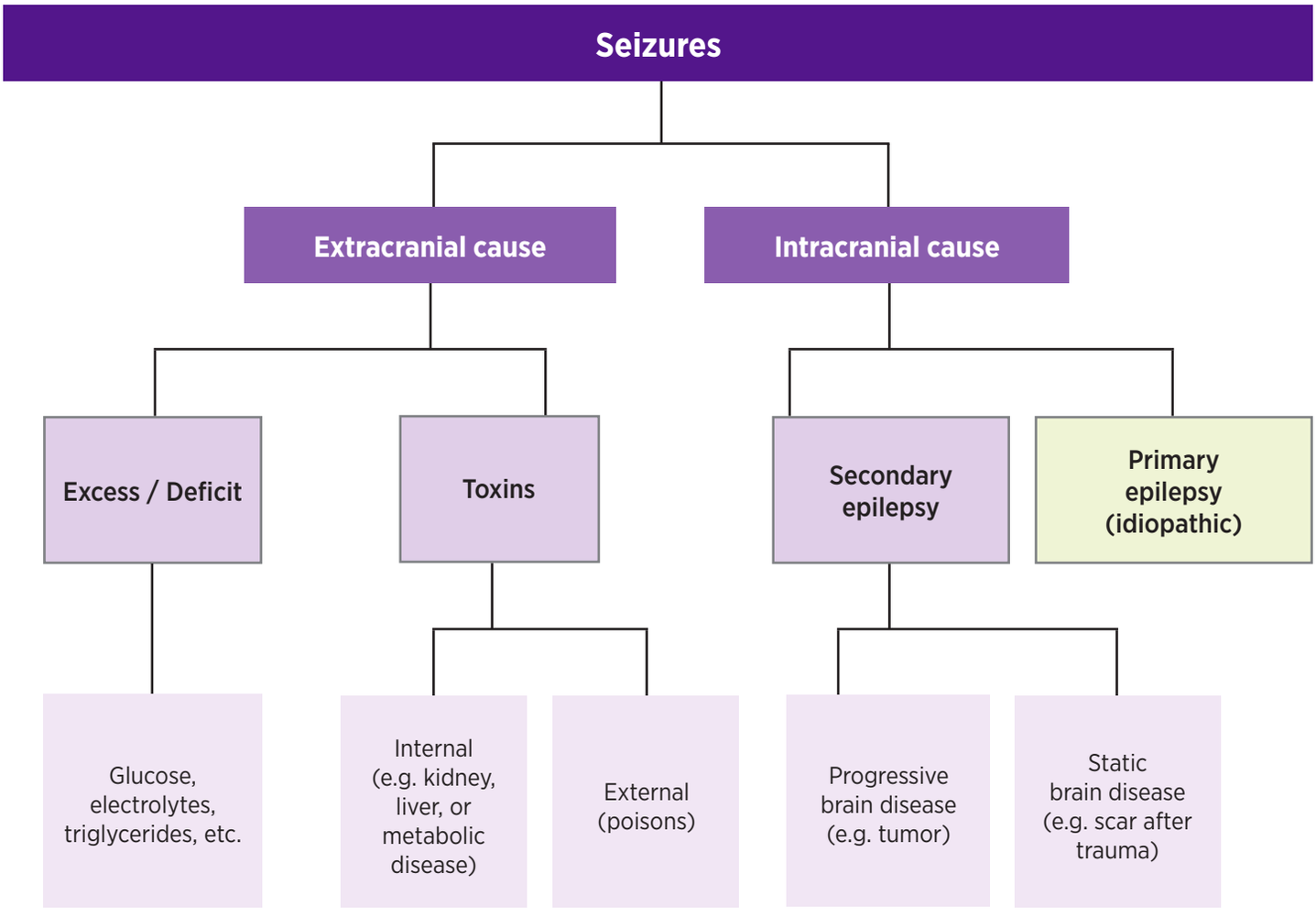
Idiopathic epilepsy is diagnosed by ruling out other diseases that manifest in epilepsy and is based on age of onset, behavior between seizures and ruling out of other acquired diseases that can manifest seizures.[3]

- Age of onset: Typically 6 months to 6 years of age
- Behavior between seizures: Neurologically normal
- Diagnostics to rule out other disease processes
  - Neurologic exam
  - CBC/Chemistry/Urinalysis
  - MRI
  - Possible cerebrospinal fluid analysis

The control of idiopathic epilepsy requires commitment to lifelong management of the condition.

Idiopathic epilepsy can be successfully controlled throughout the life of the dog with continued patient monitoring and realistic owner expectations.

Potential causes of seizures and achieving a successful diagnosis[4]



While IE is treatable, owners should realize their level of commitment.

Here are a few talking points to help initiate the discussion:

- **A pet experiencing seizures is NOT in pain – your dog does not realize they have had a seizure; it is not a quality of life issue for them.[10]**
- **Epilepsy is a chronic, lifelong condition; we cannot cure the disease, but we can control it.**
- **Appropriate control will require some trial and error to regulate the levels of medication, including multiple office visits and diagnostic tests.**
- **Seizures are a clinical sign of the disease; our goal in therapy is to decrease the number of seizures that your dog is experiencing, but we are unlikely to completely eliminate them.**
- **Understanding the key factors that play a part in owner perception of quality of life (QOL) issues for their dog may help in setting realistic expectations and help guide your conversation.**

Quality of Life – Considerations for Success

Idiopathic epilepsy is recognized as a potentially life-threatening condition—the owner's impression of the impact on the household, including emotional stress, psychosocial challenges, and economic burden, may determine the decision to treat or euthanize.[7] The lifelong control of idiopathic epilepsy requires a significant commitment from the pet owner, the burden of which can become a looming cloud.[8]

Understanding the impact on their daily lives, providing owner education, and setting appropriate expectations regarding treatment and expected outcomes—including the fact that idiopathic epilepsy is a chronic disease requiring a lifelong commitment to treatment—may result in more effective control of the disease.

An online survey study assessed the most important factors affecting quality of life (QOL) for owners of 225 dogs with idiopathic epilepsy. This study demonstrates the implications of owner perception of the dog's QOL for both the dog and the owner, and its significance in successful control of idiopathic epilepsy.

Higher QOL Significantly Associated with:[8]

- Seizure frequency – Dogs with lower average monthly seizure frequency*
- Seizure type - Dogs experiencing isolated seizures, as opposed to clusters
- Side effects – Dogs that did not experience side effects from medication
- Need to medicate during episodes – Dogs that did not require medication during an episode

*Another online survey study of 150 dog owners confirmed seizure frequency to be the most important factor affecting QOL for owners of dogs with idiopathic epilepsy.[9]

QOL WAS NOT associated with either the number of antiepileptic medications or the average monthly cost of the medication.

Potassium Bromide - The Basics

Potassium bromide (KBr), a halide salt, is considered a well-known choice for long-term control of seizures associated with idiopathic epilepsy in dogs.[11] The mean elimination half-life of KBr is 21 days.[12]

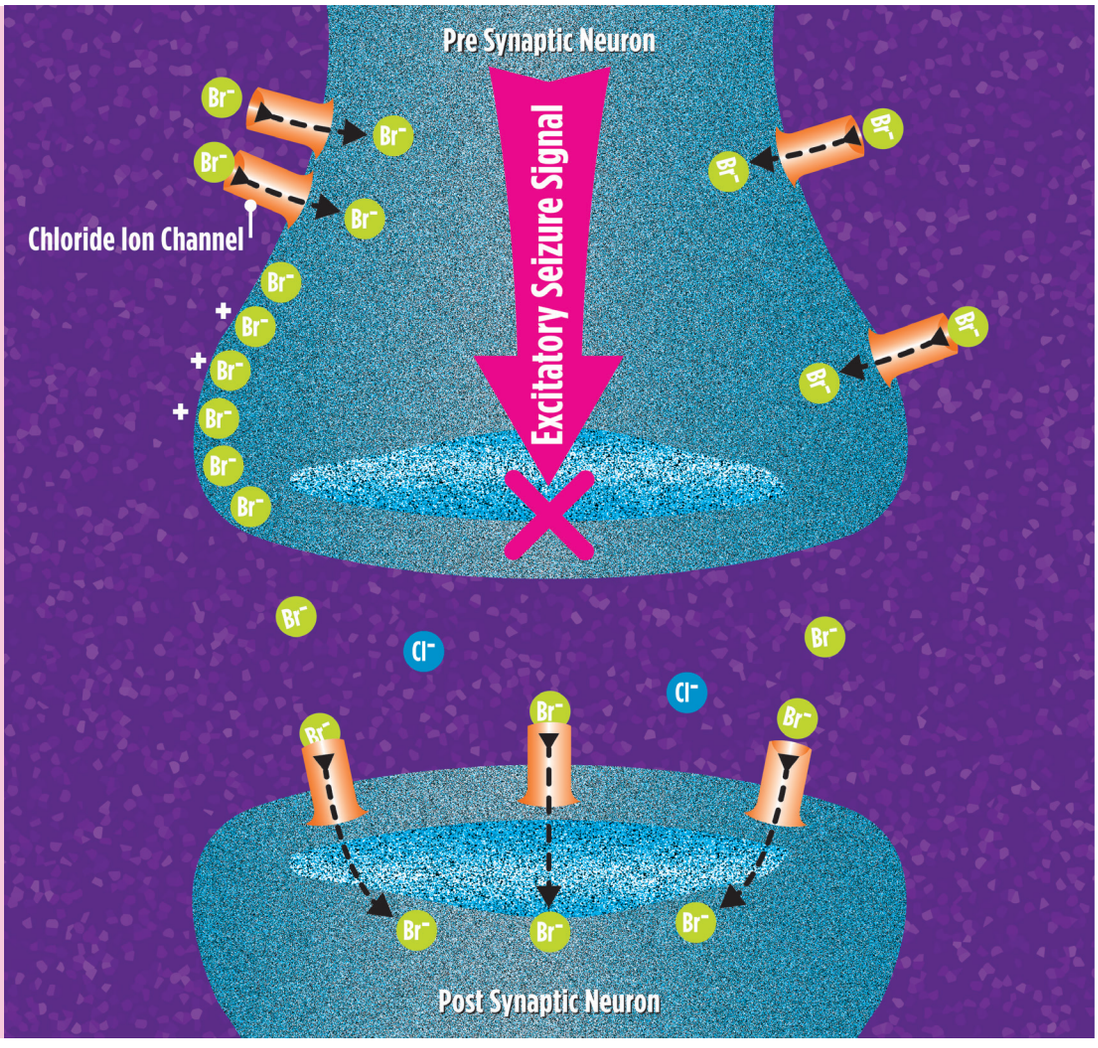
Potassium bromide does not induce or increase hepatic enzymes and is not dependent on hepatic biotransformation for metabolism and elimination.[13] Because bromide is not subject to hepatic metabolism, it is suitable for use in dogs with hepatic disease.[1, 14]

Bromide is thought to exert its antiepileptic activity by passing through the neuronal chloride ion channels, thereby hyperpolarizing neuronal membranes, raising the seizure threshold, and stabilizing neurons against excitatory input from epileptic foci.[14]

Potassium bromide does not induce or increase hepatic enzymes.

Influx of Bromide into Neuron

- **Hyperpolarizes membranes (more negatively charged)**
- **Decreases the action potential firing across the synapse**
- **Stabilizes neurons against excitatory seizure signals**



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 when changing diets, administering chloride-containing fluids, and administering concurrent medications. Careful monitoring is important in dogs that have a condition that may cause difficulty maintaining electrolyte balance.

For owners of affected dogs, the onus of idiopathic seizures can become a looming cloud.

How KBroVet®-CA1 Can Help Steady the Storm

KBroVet-CA1 has received conditional approval from the FDA for the control of seizures associated with idiopathic epilepsy in dogs. It is the first and only conditionally approved drug for idiopathic epilepsy in dogs. KBroVet-CA1 was developed to provide a consistent and reliable source of potassium bromide for veterinary patients.

What does "Conditional Approval" mean?

KBroVet-CA1 is conditionally approved by the FDA. This means that the product has been demonstrated to be safe and that there is a reasonable expectation of effectiveness, which means that the product is reasonably expected to provide the intended effect when used under the conditions of use described in the labeling. The sponsor will continue to collect the evidence of effectiveness needed for the product to receive full approval. It is a violation of Federal Law to use this product other than as directed in the labeling. Additional information on conditional approval can be found by searching http://fda.gov for "conditional approval."

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

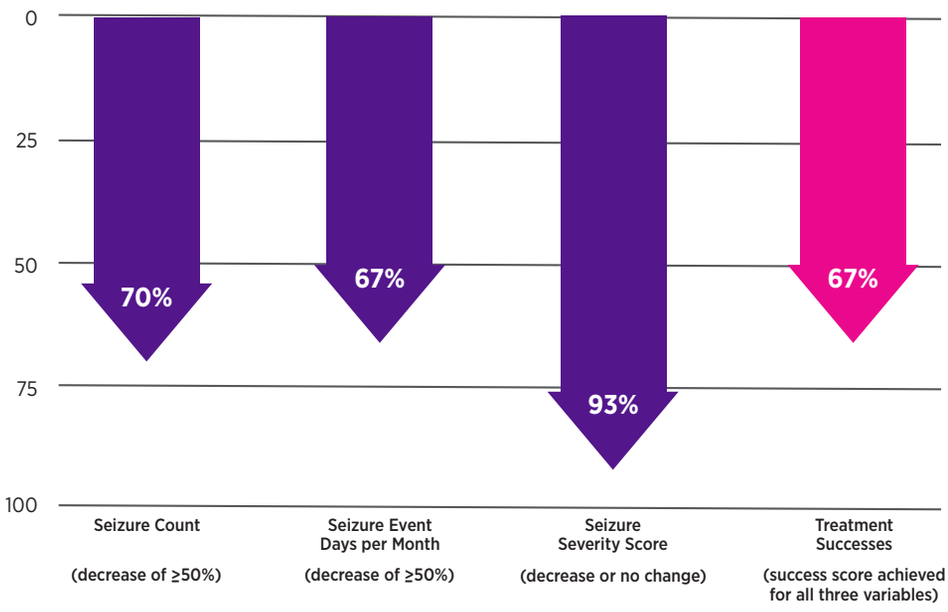
Overall reasonable expectation of effectiveness was achieved if >50% of all cases achieved a "success" score for **all three variables**.

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 anticonvulsant, 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.

Availability of an appropriately FDA-labeled, approved veterinary KBr product could provide better assurance of quality, safety, and effectiveness.

KBroVet®-CA1 is the first and only conditionally approved drug for idiopathic epilepsy in dogs.

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 with a dose of 200 to 500 mg/kg a day for 4 to 26 weeks.

Dosage & Administration

The total recommended daily dosage range of KBroVet-CA1 Chewable Tablets is 25–68 mg/kg (11–31 mg/lb) of body weight. Dosage should be adjusted based on monitoring of clinical response of the individual patient. KBroVet-CA1 Chewable Tablets may be dosed with or without food.[15] Initial loading dose regimen may be considered on an individual patient basis to balance the time required to achieve a therapeutic response while minimizing side effects.

Dog weight		No. of tablets / day	
(lb)	(kg)	250 mg Tablet	500 mg Tablet
8-23	3.6-10.4	1	
16-45	7.3-20.4		1
24-68	10.9-30.8	3	
24-68	10.9-30.8	1	1
32-91	14.5-41.3		2
40-114	18.1-51.7	1	3
40-114	18.1-51.7	1	3
48-136	21.8-61.7		3
56-159	25.4-72.1	1	3
64-182	29.0-82.6		4

KBroVet®-CA1 (potassium bromide chewable tablets)

Anti-epileptic for use in dogs only.

Conditionally approved by FDA pending a full demonstration of effectiveness under application number 141-544

CAUTION: Federal law restricts this drug to use by or on the order of a licensed veterinarian. Use only as directed. **It is a violation of Federal Law to use this product other than as directed in the labeling.**

CONTRAINDICATIONS:
KBroVet-CA1 should not be used in animals with a history of hypersensitivity to bromide.

DESCRIPTION:
KBroVet-CA1 are liver-flavored chewable tablets that contain potassium bromide (KBr). KBr is an odorless, colorless crystal or white crystalline powder or white granular solid with a pungent bitter saline taste. The molar mass of KBr is 119.002 g/mol, with high solubility in water, glycerol and ethanol.

INDICATION:
KBroVet-CA1 (potassium bromide chewable tablets) are indicated for the control of seizures associated with idiopathic epilepsy in dogs.

DOSAGE AND 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. 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.

WARNINGS:
User Safety Warnings

Not for human use. Keep out of reach of children. Contact a physician in case of accidental ingestion by humans.

Animal Safety Warnings
Not for use in cats.

Keep KBroVet-CA1 in a secured location out of reach of dogs, cats, and other animals to prevent accidental ingestion or overdose.

PRECAUTIONS:
Dogs receiving KBr should be carefully monitored 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.

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 treatment 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 with a dose of 200 to 500 mg/kg a day for 4 to 26 weeks.

ADVERSE REACTIONS:
In a retrospective field study of 51 dogs diagnosed with idiopathic epilepsy and receiving only KBr to control seizures associated with idiopathic epilepsy, adverse reactions were documented for the initial 60 days of treatment. Increased appetite, weight gain, vomiting/regurgitation and sedation were the most common clinical abnormalities documented in the 60 day period after start of KBr therapy (Table 1).

Table 1. Adverse Reactions Reported During Initial Dosing Phase (60 Day Period After Start of KBr Therapy)

Adverse Reaction	Number of Dogs with the Adverse Reaction
Increased Appetite	11
Weight Gain	8
Vomiting	5
Regurgitation	4
Sedation	3
Polydipsia	2
Ataxia	2
Polyuria	2
Weakness	2
Decreased Activity	1
Diarrhea	1
Disorientation	1
Lethargy	1
Partial Lack of Efficacy	1
Petit Mal Epilepsy	1
Seizure NOS	1
Tiredness	1
Tremors	1

Adverse reactions were also documented during the 30 days prior to KBr sample submission. Weight gain, weakness, ataxia, and increased appetite were the most common adverse reactions documented during this time period (Table 2).

Table 2. Adverse Reactions Reported During Dosing Phase (30 Day Period Before KBr Sample Submission)

Adverse Reaction	Number of Dogs with the Adverse Reaction
Weight Gain	7
Weakness	5
Ataxia	4
Increased Appetite	4
Polydipsia	3
Sedation	3
Diarrhea	2
Polyuria	2
Regurgitation	2
Vomiting	2
Decreased Appetite	1
Disorientation	1
Loose Stool	1
Panting	1
Tremors	1

Adverse events associated with concurrent use of KBr with other antiepileptic drugs such as phenobarbital have been reported. Neurologic signs were the most common adverse event and included sedation, irritability, restlessness, depression, behavioral changes, ataxia, hind limb paresis, mydriasis, stupor, and coma. The neurologic signs were reported to be reversible.

CONTACT INFORMATION:
For a copy of the Safety Data Sheet (SDS) or to report suspected adverse drug events, contact Pegasus Laboratories at 1-800-874-9764. For additional information reporting adverse drug experience reporting for animal drugs, contact FDA at 1-888-FDA-VETS or http://www.fda.gov/reportanimalae

CLINICAL PHARMACOLOGY:
Mechanism of action: KBr is a halide salt that is thought to exert its antiepileptic activity by passing through neuronal chloride ion channels, thereby hyperpolarizing neuronal membranes, raising the seizure threshold, and stabilizing neurons against excitatory input from epileptic foci.

Pharmacokinetics: The pharmacokinetics of a multi-dose regimen of administration in normal dogs have been evaluated as described in a comprehensive literature review. In one study, KBr was administered at 30 mg/kg orally every 12 hrs for a period of 115 days. Serum, urine, and cerebro-spinal fluid (CSF) bromide concentrations were measured at the onset of dosing, during the accumulation phase, at steady-state, and after a subsequent dose adjustment. Median elimination half-life and steady-state serum concentration were 15.2 days and 245 mg/dL, respectively. Apparent total body clearance was 16.4 mL/day/kg and volume of distribution was 0.40 L/kg. The CSF:serum bromide ratio at steady-state was 0.77.

Distribution, Metabolism, and Elimination: Bromide distributes into the CSF and interstitial tissues of the brain and is actively transported out of the CNS via the choroid plexus. At pharmacological doses, the active transport mechanism is overwhelmed and bromide accumulates in the brain and CSF. Bromide is not metabolized by the liver and is eliminated unchanged, primarily by renal clearance. Increased dietary consumption of chloride can promote loss of bromide in the urine, leading to a lowering of serum bromide concentrations. Decreased chloride consumption will promote increased renal reabsorption of bromide, causing an increase in bromide elimination half-life in dogs.

REASONABLE EXPECTATION OF EFFECTIVENESS:
KBroVet-CA1 is conditionally approved pending a full demonstration of effectiveness.

Additional information for Conditional Approvals can be found by searching www.fda.gov for "animal conditional approval."

Two retrospective studies were used to determine the dose and demonstrate a reasonable expectation of effectiveness for KBroVet-CA1 for the control of seizures associated with idiopathic epilepsy in dogs.

In a dose determination retrospective study, the total daily oral dose of KBr given for ≥45 days (approaching steady-state conditions) was described. To be included in this study, cases were required to meet the following eligibility requirements: samples submitted for serum bromide concentration evaluation within the required date range (January 1, 2003 to August 31, 2010), and dogs were between ≥0.5 and ≤5.0 years of age, receiving only KBr to control seizures associated with idiopathic epilepsy, administered KBr once or twice daily for ≥45 days at the dose noted on the submission form, and the serum bromide concentration was ≥0.8 and ≤3.5 mg/mL.

A total of 284 case records (58.5% male and 41.6% female), with a mean age of 3.6 years (0.7–5.0 years) and a mean body weight of 20.5 kg (1.3–88.2 kg), were evaluated between January 1, 2003 to August 31, 2010. The mean total daily oral dose was 46.6 (321.9) mg/kg with a range of 24.5–68.3 mg/kg. These results describe the total daily oral dose range to achieve serum bromide concentrations within 10% of the published therapeutic range (≥0.8 and ≤3.5 mg/mL)[1,2] for dogs with idiopathic epilepsy.

A pilot retrospective study involving review of case records of 51 client-owned dogs was conducted to evaluate the effectiveness of KBr in dogs. This retrospective study evaluated case records of dogs previously receiving only KBr to control seizures associated with idiopathic epilepsy and for which blood samples had been analyzed to quantify serum bromide concentrations for the purpose of therapeutic drug monitoring.

Seizure counts, seizure count changes, seizure event days per month and seizure severity scores were tabulated for eligible cases, comparing the 30 day period before initial treatment with KBr and the 30 day period of steady state KBr dosing. Seizure count within an individual case was required to decrease by 50% or greater in order for the case to be classified as a seizure count success. Similarly, reduction in the number of seizure event days per month by 50% was required for the case to be classified as a seizure event day count success. No increase in severity score denoted an individual case treatment success for this variable. Of the 51 evaluable cases, 27 were determined as valid for safety and effectiveness data and 24 were determined to be valid for only safety data.

Of the 27 cases, 19 (70%) were defined as "success" and 8 (30%) were defined as "failures" based on seizure count results. Eighteen (67%) were defined as "success" and 9 (33%) were defined as "failures" based on seizure event day results. Seizure severity score decreased or did not change in 25 of the 27 cases evaluated for effectiveness. Overall, of the 27 dogs included in the effectiveness analysis, 18 (67%) were considered treatment successes and 9 (33%) were considered treatment failures.

ANIMAL SAFETY:
Safety was assessed in a systematic review of literature and a retrospective field study. Reversible neurologic signs were the most consistently reported adverse effect and were generally associated with adjunctive KBr treatment or high serum bromide concentrations. Adverse effects were also seen in some dogs with low serum bromide concentration. Dermatologic and respiratory abnormalities were rare in dogs. Evidence suggested that administration of KBr with food may alleviate gastrointestinal irritation and that monitoring for polyphagia, thyroid hormone abnormalities, and high serum bromide concentrations may be beneficial.

HOW SUPPLIED:
KBroVet-CA1 are liver-flavored, non-scored tablets containing 250 mg or 500 mg of potassium bromide per tablet. KBroVet-CA1 is packaged in bottles containing 60 or 180 tablets.

500 mg Tablet (60 ct) bottle NDC 49427-324-48

250 mg Tablet (60 ct) bottle NDC 49427-323-48

500 mg Tablet (180 ct) bottle NDC 49427-324-50

250 mg Tablet (180 ct) bottle NDC 49427-323-50

STORAGE CONDITIONS: Store at controlled room temperature 20–25°C (68–77°F).

Keep out of reach of children and animals.

[1] Boothe DM. Anticonvulsant and other neurologic therapies. In: Boothe DM, Ed. Small Animal Clinical Pharmacology and Therapeutics. Philadelphia: WB Saunders Co., 2001; 431-456

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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 anticonvulsants 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,[12] the longest half-life of all seizure anticonvulsant 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 both 60 and 180 count bottles.	Variety of bottle-count sizes provides more flexibility when dispensing.

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KBroVet-CA1 Chewable Tablets have been conditionally approved by FDA pending a full demonstration of effectiveness under application number NADA 141-544.

CAUTION: Federal law restricts this drug to use by or on the order of a licensed veterinarian. Use only as directed. It is a violation of Federal Law to use this product other than as directed in the labeling.

KBroVet®-CA1
(potassium bromide chewable tablets)