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KBroVet®CA-1 Pilot Study: Efficacy & Safety Data

KBroVet-CA1 received conditional approval based on the results of a retrospective pilot study demonstrating reasonable expectation of effectiveness. Conditional approval by the FDA requires that a product has been demonstrated to be safe and that the product is reasonably expected to provide the intended effect when used under the conditions of use described in the labeling. Overall treatment success was obtained in 67% (18/27) of the case records evaluated for effectiveness of potassium bromide (KBr) in dogs.

Methodology

A retrospective pilot study was used to review the case records of 51 client-owned dogs to evaluate the reasonable expectation of effectiveness of KBr in dogs. Enrolled dogs were treated with only KBr to control the seizures associated with idiopathic epilepsy and had blood samples analyzed to quantify serum bromide concentrations for the purpose of therapeutic drug monitoring. Enrollment criteria are summarized in Table 1.

Table 1: Enrollment Criteria

Variable	Criteria
Duration of KBr dosing	Dog must have received the same total daily dose of KBr for a minimum of 60 days
Age at epilepsy diagnosis	≥0.5 years and <5 years
Concomitant therapy	Dog administered ONLY KBr (monotherapy)
Serum bromide concentration range	≥0.8 mg/mL and ≤3.5 mg/mL

Variables, including seizure counts, seizure event days per month, and seizure severity scores, in the 30-day period before initial treatment were compared to those in the 30-day period of steady-state KBr dosing. To qualify as a success each variable was required to meet the criteria in Table 2.

Table 2: Variable Criteria Measured to Qualify as a Success

Variable	Criteria
Seizure Count	Decrease by ≥50%
Seizure Event Days	Reduction of event days per month by ≥50%
Seizure Severity Score	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

Of the 51 cases, 27 were determined as valid for both safety and effectiveness data and 24 were determined to be valid for only safety data. A total of 61% were male dogs, the mean age of epilepsy onset was 2.1 years, and the mean age of initiation of KBr treatment was 2.4 years. Approximately 67% of the 27 cases submitted for efficacy data were dosed once daily and 33% were dosed twice daily, with a mean maintenance dose of 37 mg/kg/day. Clinical findings were documented for the initial 60 days of KBr treatment.

Efficacy (27 dogs)

Based on seizure count results, 19 (70%) were defined as successes and 8 (30%) were defined as failures. Based on seizure event days per month, 18 (67%) were defined as successes and 9 (33%) were defined as failures. Seizure severity scores decreased or did not change in 25 of the 27 cases (93%) evaluated for effectiveness. Overall, 18 of the 27 dogs (67%) were considered treatment successes and 9 (33%) were considered treatment failures.

Safety (51 dogs)

The clinical abnormalities documented most in the 60-day period following the initiation of KBr therapy included increased appetite, weight gain, vomiting/regurgitation, and sedation.

Table 3: Summary of Results

Efficacy Variable	Success
Seizure Count	70% (19/27)
Seizure Event Days	67% (18/27)
Seizure Severity Score	93% (25/27)
Overall Treatment Success	67% (18/27)

Safety
Most common abnormalities included increased appetite, weight gain, vomiting/regurgitation, and sedation.

Conclusion

Overall treatment success was obtained by 67% (18/27) of the dogs. Based on the results of this retrospective pilot study, KBroVet-CA1 demonstrated a reasonable expectation of effectiveness, at the total recommended oral daily dosage of 25-68 mg/kg (11-31 mg/lb), for the control of seizures associated with idiopathic epilepsy in dogs.

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