Efficacy and safety of porcine insulin zinc suspension (IZS-P) for reducing hyperglycemia and associated clinical signs in cats with diabetes mellitus

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Abstract
An unmasked, multi-center, historical control, unmasked clinical study was conducted to provide substantial evidence of the clinical effectiveness and safety of porcine insulin zinc suspension (IZS-P, Vetsulin®) for reducing hyperglycemia and its associated signs in cats with diabetes mellitus. The study was conducted in accordance with the current FDA, CVMP and WHO Guidance on Good Clinical Practice.

Materials & Methods
Study design
• Multi-center, historical control, unmasked clinical study
• Inclusion criteria on prior treatment or with coexisting primary diseases were excluded. A baseline blood glucose curve (Day 0) was completed and IZS-P therapy (approximately 1 to 2 IU per subcutaneous injection) was initiated. Glucose curves and clinical signs were re-evaluated on Days 7, 14 ± 2 days and 60 and the dose was adjusted accordingly. Overall response to treatment in each cat was read on a visual analog scale (VAS). Additional examinations to assess the long-term safety were carried out at 90, 120 and 150 days. Complete blood count (CBC) and serum chemistry were performed during the course of the study and urinalysis prior to enrollment.

Inclusion criteria
• Cats were enrolled based on elevated fasting blood glucose (>250 mg/dL on two occasions) and/or hyperglycemia (in cats with insulin treated diabetes mellitus).

Exclusion criteria
• Treatment with another insulin for longer than 1 week
• Inadequate evaluation of glycemic control
• Clinical signs of anemia/leukopenia, active pancreatitis, hyperadrenocorticism, acromegaly, mega or small colon, macro angiopathy
• Treatment with corticosteroids, progesterone or estrus
• Polyneuropathy was documented in 5.1% (4/78) of the cats. Two injection site reactions were reported (mild bruising at the injection site, mildly thickened subcutis).

Evaluation of efficacy and safety
• Blood glucose curve
• Clinical signs
• Diabetes control evaluation:

Study population
• Starting dose: 1 to 2 IU IZS-P twice daily by subcutaneous injection, 2 to 5 cm from the dorsal midline, respectively (n=77; Day 0) and n=76 (Day 60), respectively (n=77; both days).
• Mean blood glucose was <5.25, 75.1 and 74.3 mg/dL of the cats and blood glucose was <50 mg/dL in 80%, 72.4 and 69.3% of the days on Days 0, 60 and 180, respectively. Mean fructosamine concentration decreased from 604.3 µmol/L on Day 0 to 451.3 µmol/L on Day 60 and 180, respectively (p<0.001 both days). Mean glucose nadir decreased from 394.1 mg/dL on Day 0 (n=77) to 216.7 mg/dL (n=76) and 219.5 mg/dL (n=73) on Days 60 and 180, respectively. Mean fructosamine concentration decreased from 604.3 µmol/L on Day 0 to 451.3 µmol/L on Day 60 and 180, respectively (p<0.001 both days). Diabetes remission occurred in four cats. Less than 3.9 (2/77) of the cats failed to respond to treatment.

Discussion
Porcine insulin zinc suspension (IZS-P) was effective for the first time in the early 1990’s by Dutschke® (Intervet International bv, The Netherlands) and is registered for dogs and cats as Caninsulin® in more than 50 countries. IZS-P is safe and effective in cats when dosed Appropriately and well monitored.

Introduction
Porcine insulin zinc suspension (IZS-P) was effective for the first time in the early 1990’s by Dutschke® (Intervet International bv, The Netherlands) and is registered for dogs and cats as Caninsulin® in more than 50 countries. IZS-P is safe and effective in cats when dosed Appropriately and well monitored.

The current study confirmed that IZS-P is effective and safe for reducing hyperglycemia and associated clinical signs in cats with diabetes mellitus.

Conclusions
The effect of IZS-P therapy on reducing hyperglycemia and hyperglycemic associated signs was confirmed in this study. Cats enrolled in the study had a mean age of 6.9 ± 4.1 years, with 32% spayed female, 68% castrated male, 3 to 17.5 years old.

Acknowledgments
The authors thank Intervet, Inc. for financial support. The authors wish to thank all the cat owners, their veterinarians, the coaching team and the study team for their participation in the study.

References