FEEL BETTER, MY BEST FRIEND!

Spike the Dog Has Diabetes
Spike the dog and Sugar the cat are best friends. They do everything together! They eat, drink, sleep, play, and run around the house. It’s fun because they have each other.

One day, Spike didn’t want to play with Sugar. He only wanted to take a nap. The next day, it was the same.

“What’s wrong, Spike?” asked Sugar. “Why do you sleep so much?” “Why are you so thirsty all of the time?” “Why do you have to go to the bathroom so much?”

Spike was confused. Why didn’t he feel good anymore?

His owner noticed these signs, too, and took him to visit Dr. Furry the veterinarian.
Dr. Furry told Spike he needed a blood test and a urine test to see what was wrong, to see if Spike had a disease called diabetes.

“What’s diabetes?” asked Spike.

“Diabetes is a disease in which your body does not properly process food for use as energy. Most of the food we eat is turned into glucose, or sugar, for our bodies to use for energy,” said Dr. Furry.

Spike’s owner didn’t realize he had diabetes because the signs weren’t obvious.

But, once Spike started getting treated with a medicine called Vetsulin®, he felt so much better.

Spike’s owner gives him the medicine and tests his sugar levels, just like humans that have diabetes. Spike can still live a happy and healthy life with diabetes—and spend time with his best friend Sugar!
FULL PRESCRIBING INFORMATION
DESCRIPTION

vetsulin® is a sterile aqueous zinc suspension of purified porcine insulin. Each mL contains:

- purified porcine insulin (35% amorphous and 65% crystalline): 40 IU
- 0.08 mg zinc (as zinc acetate hydrate)
- 7.0 mg Sodium acetate trihydrate
- 1.36 mg Sodium chloride
- 1.0 mg Methylparaben (preservative)
- 0.7 mg insulin suspensions: do not use the product if visible clumps or white particles persist after shaking thoroughly.

Shake the vial thoroughly until a homogeneous, uniformly milky suspension is obtained. Foam on the surface of the suspension formed during shaking should be allowed to disperse before the product is used and, if required, the product should be gently mixed to maintain a homogeneous, uniformly milky suspension before use. Clumps or white particles can form in insulin suspensions: do not use product if visible clumps or white particles persist after shaking thoroughly.

Cartridges: vetsulin® CARTRIDGES SHOULD BE USED EXCLUSIVELY with VetPen™ and, if required, the product should be gently mixed to maintain a homogeneous, uniformly milky suspension. In case of accidental injection, seek medical attention immediately. Exposure to product may induce a local or systemic allergic reaction in sensitized individuals.

INDICATION

vetsulin® (porcine insulin zinc suspension) is indicated for the reduction of hyperglycemia and hyperglycemia-associated clinical signs in dogs and cats with diabetes mellitus.

DOSAGE AND ADMINISTRATION

For subcutaneous injection in DOGS and CATS ONLY

Vials: USE OF A SYRINGE OTHER THAN A U-40 SYRINGE WILL RESULT IN INCORRECT DOSING. Shave the vial thoroughly until a homogeneous, uniformly milky suspension is obtained. Foam on the surface of the suspension formed during shaking should be allowed to disperse before the product is used and, if required, the product should be gently mixed to maintain a homogeneous, uniformly milky suspension before use. Clumps or white particles can form in insulin suspensions: do not use product if visible clumps or white particles persist after shaking thoroughly.

Cartridges: vetsulin® CARTRIDGES SHOULD BE USED EXCLUSIVELY WITH VETPEM™ and 29G/12 MM PEN NEEDLES. Prior to loading vetsulin® cartridges, shake the cartridge until a homogeneous, uniformly milky suspension is obtained. Clumps or white particles can form in insulin suspensions: do not use product if visible clumps or white particles persist after shaking thoroughly.

The detailed instructions for use provided with VetPen™ should be strictly followed.

The injection should be administered subcutaneously, 2 to 5 cm (3/4 to 2 in) from the dorsal midline, varying from behind the scapulae to the mid-lumbar region and alternating sides. Always provide the Owner Information Sheet with each prescription.

Dogs

The initial recommended vetsulin® dose is 0.5 IU insulin/kg body weight. This dose should be given once daily concurrently with, or right after a meal.

Twice daily therapy should be initiated if the duration of insulin action is determined to be inadequate. If twice daily treatment is initiated, the two doses should each be 25% less than the once daily dose required to attain an acceptable nadir. For example, if a dog receiving 20 units of vetsulin® once daily has an acceptable nadir but inadequate duration of activity, the vetsulin® dose should be changed to 15 units twice daily.

The veterinarian should re-evaluate the dog at appropriate intervals and adjust the dose based on clinical signs, urinalysis results, and glucose curves until adequate glycemic control has been attained. Further adjustments in dosage may be necessary with changes in the dog’s diet, body weight, or concomitant medication, or if the dog develops concurrent infection, inflammation, neoplasia, or an additional endocrine or other medical disorder.

Cats

The initial recommended dose in cats is 1 to 2 IU per injection. The injections should be given twice daily at approximately 12 hour intervals. For cats fed twice daily, the injections should be given concurrently with, or right after each meal. For cats fed ad libitum, no change in feeding schedule is needed.

The veterinarian should re-evaluate the cat at appropriate intervals and adjust the dose based on clinical signs, urinalysis results, and glucose curve values until adequate glycemic control has been attained. Further adjustments in dosage may be necessary with changes in the cat’s diet, body weight, or concomitant medication, or if the cat develops concurrent infection, inflammation, neoplasia, or an additional endocrine or other medical disorder.

CONTRAINDICATIONS

Dogs and cats known to have a systemic allergy to pork or pork products should not be treated with vetsulin®. vetsulin® is contraindicated during periods of hyperglycemia.

WARNINGS

User Safety: For use in animals only. Keep out of the reach of children. Avoid contact with eyes. In case of contact, immediately flush eyes with copious amounts of water for 15 minutes. Accidental injection may cause local hypoglycemia. In case of accidental injection, seek medical attention immediately. Exposure to product may induce a local or systemic allergic reaction in sensitized individuals.

Animal Safety: Owners should be advised to observe for signs of hypoglycemia (see Owner Information Sheet). Use of this product even at established doses, has been associated with hypoglycemia. An animal with signs of hypoglycemia should be treated immediately. Glucocorticoids (deemed as blood glucose - 50 mg/dL) with or without associated clinical signs occurred in 35.5% (22/62) of the dogs at various times during the study. Clinical signs of hypoglycemia were generally mild in nature (described as weakness, lethargy, stumbling, falling down, and/or depression). Discontinuation and collapse were reported less frequently and occurred in 16.1% (10/62) of the dogs. Two dogs had a seizure and one dog died during the seizure. Although not confirmed, the presumptive diagnosis was hypoglycemia-induced seizures. In the rest of the dogs, hypoglycemia resolved with appropriate therapy and adjustments in insulin dosage.

Use in puppies and kittens: The safety and effectiveness of vetsulin® in these age groups and in lactating cats and has not been evaluated.

ADVERSE REACTIONS

Dogs

In the field effectiveness and safety study, 68 dogs were treated with vetsulin®. Sixty-two dogs were included in the assessment of safety. Hypoglycemia (defined as blood glucose - 50 mg/dL) with or without associated clinical signs occurred in 35.5% (22/62) of the dogs at various times during the study. Clinical signs of hypoglycemia were generally mild in nature (described as weakness, lethargy, stumbling, falling down, and/or depression). Discontinuation and collapse were reported less frequently and occurred in 16.1% (10/62) of the dogs. Two dogs had a seizure and one dog died during the seizure. Although not confirmed, the presumptive diagnosis was hypoglycemia-induced seizures. In the rest of the dogs, hypoglycemia resolved with appropriate therapy and adjustments in insulin dosage.

In a 21-day field safety and effectiveness study, 40 dogs, already well controlled on vetin>({eq}®{eq}) were administered vetsulin® using a VetPen™ insulin pen loaded with a pre-filled 2.7 mL vetsulin® cartridge and 29 gauge/12 mm pen needles. All dogs enrolled in the study were being treated with a single route. No significant loss of diabetic control was reported in 10 dogs, 3 of which were withdrawn from the study. Four dogs’ loss of control resolved after dose adjustment while still using the insulin pen. For the remaining 3 dogs, the loss of diabetic control was reported at the end of the study and outcome was not documented. Two dogs had injection site reactions: edema in one dog and two instances of crusting in another. Poor appetite and weight loss was reported in one dog.
In a 21-day field safety and effectiveness study, 36 cats, already well controlled on vetsulin®, were administered valsulin® using a VePen® insulin pen loaded with a pre-filled 2.7 mL vetsulin® cartridge and 29 gauge/12 mm pen needles. Thirty-six owners (100%) said they were able to learn how to use the pen. Thirty-four owners (94.4%) said the pen was well tolerated by the cats. For thirty-three owners (91.7%), the investigators said that the diabetes was not negatively affected by the use of the pen.

**HUMAN STUDIES**

**HUMAN DATA**

**NONCLINICAL TOXICOLOGY**

**Pathology**

No toxicology studies are available for the insulin pen needles, cartridge, and pre-filled insulin cartridges. The studies evaluated for insulin are available for the commercial insulin product. The type of data generated is limited to 50 cats and does not include a statistically valid number of cats to be representative of the typical diabetic cat population.

**ADVERSE REACTIONS**

**Adverse drug experiences**

Merck received adverse drug experience reports from forty-eight owners of veterinary animals treated with veterinary insulin products during the period from January 1, 1998 to July 31, 2007. The adverse drug experiences include reports of insulin allergy. The most commonly reported adverse drug experiences were:

- **In clinical studies:**
  - Hypoglycemia was reported in one cat. The cat recovered following symptomatic treatment and/or dose adjustment.
  - Hypoglycemia was reported in one cat.
  - The cat recovered following symptomatic treatment and/or dose adjustment.

- **In field studies:**
  - Hypoglycemia was reported in one cat. The cat recovered following symptomatic treatment and/or dose adjustment.

**Adverse drug experiences in cats**

In a 21-day field safety and effectiveness study, 36 cats, already well controlled on vetsulin®, were administered valsulin® using a VePen® insulin pen loaded with a pre-filled 2.7 mL vetsulin® cartridge and 29 gauge/12 mm pen needles. Thirty-six owners (100%) said they were able to learn how to use the pen. Thirty-four owners (94.4%) said the pen was well tolerated by the cats. For thirty-three owners (91.7%), the investigators said that the diabetes was not negatively affected by the use of the pen.

**STORAGE CONDITIONS**

Store in an upright position under refrigeration at 2°C to 8°C (36°F to 46°F). Do not freeze. Protect from light. The loaded VePen® can be stored on its side.

**Use contents within 42 days of first puncture.**

**Additional information about vetsulin®, VePen®, and diabetes mellitus can be found at www.vetsulin.com**

Distributed by: Intervet Inc (d/b/a Merck Animal Health), Madison, NJ 07940

Made in Germany

09/13

© Copyright 2014 Intervet Inc., a subsidiary of Merck & Co., Inc. All rights reserved.

Intervet Inc (d/b/a Merck Animal Health), Madison, NJ 07940

152234 R1

CPN: 10474305
Vetsulin® (porcine insulin zinc suspension) important safety information

Vetsulin should not be used in dogs or cats known to have a systemic allergy to pork or pork products. Vetsulin is contraindicated during periods of hypoglycemia. Keep out of reach of children. As with all insulin products, careful patient monitoring for hypoglycemia and hyperglycemia is essential to attain and maintain adequate glycemic control and prevent associated complications. Overdosage can result in profound hypoglycemia and death. The safety and effectiveness of Vetsulin in puppies and kittens, breeding, pregnant, and lactating dogs and cats has not been evaluated. See package insert for full information regarding contraindications, warnings, and precautions.

*Vetsulin is known as Caninsulin outside of the US.