A DOG OWNER’S GUIDE.
Vetsulin® can help your diabetic dog lead a healthy, normal life.

Vetsulin fits the lifestyle YOU LOVE SHARING with your dog.
Your dog has diabetes mellitus.

It can be a shock to learn that your dog has diabetes. Fortunately, diabetes in dogs can be managed successfully with insulin therapy, diet, and exercise. Your veterinarian can help make this possible with Vetsulin® (porcine insulin zinc suspension).

WHAT IS DIABETES MELLITUS?

During digestion, carbohydrates in your dog’s food are converted into various sugars, including glucose. Glucose is absorbed into the blood and provides energy to the body’s cells.

However, glucose can’t enter most cells without insulin, a hormone produced in the pancreas. When the pancreas produces little or no insulin, glucose cannot enter the body’s cells and accumulates in the blood. The result is diabetes mellitus. Simply put, diabetes results from a shortage of insulin.

YOUR DOG CAN LIVE A HEALTHY LIFE WITH DIABETES!

In general, diabetes can’t be cured. The good news is that, with some changes in your dog’s care and daily doses of Vetsulin, your dog will most likely be able to lead a normal, healthy life.

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®—just what your diabetic dog needs.

Vetsulin® (porcine insulin zinc suspension) is the only FDA-approved insulin for dogs, and it has been used successfully to treat dogs for more than 20 years worldwide.* You can take comfort in knowing that Vetsulin is the closest thing to a dog’s own insulin.

Your veterinarian will determine the dose that’s right for your dog and will teach you everything you need to know about administering the injection and monitoring your dog’s blood glucose level. Based on blood glucose levels, your veterinarian will adjust the dose until the correct dose is established. This time period can vary from 1 week to 1 or 2 months.

Look ahead with optimism.

Although Vetsulin is not a cure for diabetes, it can help control or eliminate many of the signs associated with the disease (such as excessive thirst, urination, and weight loss) and prevent development of life-threatening complications. The response to Vetsulin varies from dog to dog but can be quite dramatic. In most dogs, improvement can be seen within a few days.

If Vetsulin is not given as directed, signs of diabetes will return, and complications may develop. Once stabilized on insulin, most dogs are able to lead a happy, healthy life.

The life expectancy of dogs on insulin can be similar to that of other healthy dogs when diabetes is well managed.

Making small changes for the better.

Your veterinarian may ask you to take the following actions to help manage your dog’s diabetes:

- Change the times, amounts, and brand of food you feed your dog
- Ask family and friends to join you in eliminating extra dog treats
- Monitor your dog’s exercise, keeping it regular and routine
- Monitor your dog’s blood and urine glucose

*Vetsulin is sold as Caninsulin® outside of the US.
Avoiding possible complications.

The most common side effect experienced with Vetsulin® (porcine insulin zinc suspension) therapy or other insulin preparations is low blood sugar, also called hypoglycemia. When untreated, hypoglycemia can be fatal. Fortunately, knowing its causes can help you avoid unnecessary occurrences of hypoglycemia.

- Giving too much insulin
- Missing or delaying food
- Change in food, diet, or amount fed
- Increase in exercise
- Infection or illness
- Change in the body’s need for insulin
- Adrenal, pituitary, or thyroid gland diseases or progression of liver or kidney disease
- Interaction with other drugs

**SIGNS OF HYPOGLYCEMIA** may occur suddenly and can include:

- Weakness
- Depression
- Behavioral changes
- Muscle twitching
- Anxiety
- Seizures
- Coma
- Death

What to do if hypoglycemia occurs.

**IF YOUR DOG IS CONSCIOUS:**

1. Rub about 1 tablespoon of corn syrup on your dog’s gums.
2. When your dog is able to swallow, feed the dog its usual meal.
3. Contact your veterinarian.

**IF YOUR DOG IS UNCONSCIOUS OR HAVING A SEIZURE:**

This is a medical emergency.

**CONTACT YOUR VETERINARIAN.**

**IN THE MEANTIME:**

1. Treat your dog immediately. Do not delay treatment.
2. If your dog is unconscious, pour a small amount of corn syrup onto your finger and rub it onto your dog’s gums.
3. The sugar is absorbed very quickly (1–2 minutes), after which your dog should respond.
4. Do not pour the solution directly in your dog’s mouth, since there is a risk it could be inhaled into the lungs.
5. Once your dog has responded and is sitting up, feed it a small amount of its usual meal.
6. When your dog is stabilized, immediately take him or her to your veterinarian for evaluation.
vetsulin®
(porcine insulin zinc suspension)

NADA 141-236, Approved by FDA

CAUTION
Federal law restricts this drug to use by or on the order of a licensed veterinarian.

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.

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 hypoglycemia.

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 clinical 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. Glucose should be given orally or intravenously as dictated by clinical signs. Insulin should be temporarily withheld and, subsequently, the dosage should be adjusted, if indicated. Any change in insulin should be made cautiously and only under a veterinarian’s supervision. Changes in insulin strength, manufacturer, type, species (animal, human) or method of manufacture (rDNA versus animal-source insulin) may result in the need for a change in dosage.

Appropriate diagnostic tests should be performed to rule out endocrinopathies in pets that are difficult to regulate (e.g., hyperadrenocorticism in dogs and hyperthyroidism in cats).

PRECAUTIONS
Animals presenting with severe ketoacidosis, anorexia, lethargy, and/or vomiting should be stabilized with short-acting insulin and appropriate supportive therapy until their condition is stabilized. As with all insulin products, careful patient monitoring for hypoglycemia and hyperglycemia are essential to attain and maintain adequate glycemic control and prevent associated complications. Overdosage can result in profound hypoglycemia and death. Progestogens, certain endocrinopathies, and glucocorticoids can have an antagonistic effect on insulin activity. Intact bitches should be ovariohysterectomized. Progestogen and glucocorticoid use should be avoided.

Drug Interactions:
In the US clinical effectiveness studies, dogs and cats received various medications while being treated with vetsulin® including antimicrobials, antivirals, antifungals, analgesics, anesthetics/tranquilizers, diuretics, bronchodilators, corticosteroids (cats), NSAIDs, thyroid hormone supplementation, hyperthyroid medication (methimazole), internal and external parasiticides, anti-emetics, dermatological topical treatments and oral supplements, ophthalmic preparations containing antimicrobials and antiinflammatories, and various vaccines. No medication interactions were reported. This drug was not studied in dogs receiving corticosteroids.

Reproductive Safety: The safety and effectiveness of vetsulin® in breeding, pregnant, and lactating dogs and cats has not been evaluated.

Use in puppies and kittens: The safety and effectiveness of vetsulin® in puppies and kittens has not been evaluated.

ADVERSE REACTIONS
Dogs
In the field effectiveness and safety study, 66 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). Disorientation 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 never confirmed, the presumptive diagnosis was hypoglycemia-induced seizures. In the rest of the dogs, hypoglycemia resolved with appropriate therapy and adjustments in insulin dosage. Seven owners recorded the following observations about the injection site on the home monitoring forms: swollen, painful, sore, and a bleb under the skin.

The following clinical observations occurred in the field study following treatment with vetsulin® and may be directly attributed to the drug or may be secondary to the diabetic state.
or other underlying conditions in the dogs: hematuria, vomiting, diarrhea, pancreatitis, non-specific hepatopathy/pancreatitis, development of cataracts, and urinary tract infections.

In a 21-day field safety and effectiveness study, 40 dogs, already well controlled on vetsulin®, 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 evaluated for safety. 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.

**Cats**

In a field effectiveness and safety study, safety data was reported for 78 cats receiving vetsulin®. Hypoglycemia (defined as blood glucose < 50 mg/dL) was reported in 61 cats (88 total incidences). Fifteen of the occurrences (involving 13 cats) were associated with clinical signs described as lethargy, diarrhea, decreased appetite/anorexia, vomiting, and hypothermia. One cat had seizures following accidental overdosing by the owner and again during the subsequent dose adjustment period. The cat responded to supportive therapy and had no further hypoglycemic episodes. In all cases of hypoglycemia, the clinical signs resolved following symptomatic treatment and/or dose adjustment. Polyneuropathy was reported in 4 cats. Two injection site reactions were reported: one as a mildly thickened subcutaneous tissue reaction and the second as a mild bruising.

The following clinical observations occurred in the field study following treatment with vetsulin® and may be directly attributed to the drug or may be secondary to the diabetic state or other underlying conditions in the cats: foul odor to stool, diarrhea, dull coat, rapid, shallow breathing, stiff gait in rear, gallop rhythm, and pruritus with alopecia.

During the 1998–2007 period, the following adverse events in 50 cats treated with porcine insulin zinc suspension were reported to Intervet International and Intervet Inc: Death, seizures, lack of effectiveness/dysregulation, hypoglycemia, allergic or skin reaction, lethargy, vomiting/diarrhea, injection pain, hyperthermia, nystagmus, PU/PD, and abnormal behavior.

In a 21-day field safety and effectiveness study, 36 cats, already well controlled on vetsulin®, 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. Loss of diabetic control was reported in three cats all of which resolved after dose adjustment while still using the insulin pen. Hypoglycemia was reported in one cat. The cat recovered with supportive care and dose adjustment.

To report suspected adverse drug experiences, call Merck at 1-800-224-5318.

For additional information about adverse drug experience reporting for animal drugs, contact FDA at 1-888-FDA-VETS, or http://www.fda.gov/AnimalVeterinary/SafetyHealth

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

**Supplied:** 10 ml vial and 2.7 cartridge

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

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For more information about Vetsulin® (porcine insulin zinc suspension) and diabetes mellitus in dogs, visit www.vetsulin.com.