Caninsulin® PORCINE INSULIN ZINC INJECTION (Mfr. Std.) For Veterinary Use Only

STERILE SUSPENSION 40 I.U./ML

Owner Information about Caninsulin®

Caninsulin® is for the control of hyperglycemia associated with diabetes mellitus in dogs and cats.

This summary contains important information about Caninsulin®. You should read this information before you start giving your pet Caninsulin® and review it on a regular basis. This sheet is provided only as a summary and does not take the place of instructions from your veterinarian. Talk to your veterinarian if you do not understand any of this information or if you want to know more about Caninsulin®.

What is Caninsulin®?

Caninsulin® is an aqueous suspension of porcine (pork) insulin. Insulin is a hormone produced by the pancreas (a large gland that lies near the stomach). This hormone is necessary for the body's correct use of food, especially sugar.

What is Diabetes mellitus?

Diabetes mellitus (DM) occurs when a pet has inadequate levels of or an abnormal response to insulin. DM is common in middle age and older pets. Daily insulin injections are usually necessary to treat DM. Caninsulin® may help your pet effectively use food, aid in maintaining an acceptable blood sugar (glucose) level, and reduce or eliminate clinical signs commonly seen in pets with DM. Diabetes mellitus may cause some or all of these signs or changes in your pet:

- Excessive thirst (Polydipsia)
- Excessive urination (Polyuria)
 Excessive appetite (Polyphagia)
- · Weight loss despite good appetite
- Glucose in the urine (Glycosuria)
- Ketones in the urine (Ketonuria)
- Cloudy eyes and vision loss (Diabetic cataracts)

Untreated or improperly regulated diabetes mellitus may lead to changes in the acidity of the blood (diabetic ketoacidosis) with dehydration, vomiting, weakness, depression, coma and death.

What kind of results can I expect when my pet is on Caninsulin® for **Diabetes mellitus?**

Although Caninsulin® is not a cure for DM, it can help control or eliminate many of the complications associated with the disease (such as excessive thirst, urination, and weight loss) and prevent development of life threatening ketoacidosis.

- Response varies from pet to pet but can be guite dramatic.
- In most pets, improvement can be seen within a few days.

• If Caninsulin® is discontinued or not given as directed, the signs of Diabetes mellitus will likely return and life-threatening complications such as ketoacidosis may develop.

Who should not receive Caninsulin®?

• Pets known to have a systemic allergy to pork or pork products.

· Pets that have stopped eating or have greatly decreased appetite (anorexia), pets that are vomiting, pets that show signs of extreme drowsiness or fatigue (lethargy) and/or pets showing signs of severe ketoacidosis, should not receive Caninsulin® until stabilized with appropriate supportive therapy.

• Caninsulin® is for use in animals only. Keep out of reach of children. Seek medical attention immediately if accidental injection occurs.

What to tell/ask your veterinarian before using Caninsulin®? Talk to your veterinarian about:

- The signs of DM you have observed.
- What tests might be done before Caninsulin® is prescribed.
- The importance of spaying, if your pet is an intact female.

• The importance of consistent daily injections, an appropriate and consistent diet, weight control, exercise and home monitoring of your pet's condition.

• How often your pet may need to be examined by your veterinarian.

• The risks and benefits of using Caninsulin®. Tell your veterinarian if your pet has ever had the following medical

problems: · Side effects when receiving other insulin products

- Digestive upset (vomiting and/or diarrhea)
- Liver disease
- Inflamed pancreas (Pancreatitis)
- Underactive thyroid (Hypothyroidism)
- Cushing's Syndrome (Hyperadrenocorticism)
- Kidney disease
- Tell vour veterinarian about:

• Any medical problems or allergies that your pet has now or has had. • All medicines that you are giving your pet or plan to give your pet, including those you can get without a prescription.

How to give Caninsulin® to your pet?

Doses of insulin are measured in units. Caninsulin contains 40 units/mL of insulin (1 mL = 1cc). Use Caninsulin® vials with U-40 syringes only. Use of a syringe other than a U-40 syringe will result in incorrect dosing. The Caninsulin® cartridge is designed to be used only with VetPen[™] and 29G/12 mm single use needles. VetPen[™] is accompanied by a package leaflet with detailed instructions for use to be followed. Caninsulin® should be administered according to your veterinarian's instructions.

Your veterinarian will determine the amount of insulin needed (based on the weight of your pet, clinical signs such as water consumption, and laboratory results), instruct you on proper storage and handling, show you how to draw the insulin from the vial or how to use the VetPen™, and instruct you on how to administer the injection. Once you can do this correctly, your veterinarian will provide you with everything you need to care for your pet at home. Caninsulin® should be administered according to the following instructions:

Preparing the Dose:

- · Wash your hands
- Remove the Caninsulin® vial or cartridge from the refrigerator

· 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. In case the suspended particles have settled during the waiting period, the product should be mixed again, gently this time, prior to use, to maintain a homogeneous, uniformly milky suspension.

Turn the cartridge up and down at least 10 times until the insulin appears uniformly milky. Do not use if clumps, particles, or flocculation are visible after mixing.

Caninsulin® vials

•Carefully remove the cap from the needle.

 Using a U-40 insulin syringe, pull the plunger back to draw air into the syringe to equal the Caninsulin® dose.

• Insert the syringe into the bottle and inject the air into the bottle.

· Turn the bottle and syringe upside down. Making sure the tip of the needle is in the Caninsulin®, withdraw the correct dose into the syringe. · Before removing the needle from the bottle, check the syringe for any air bubbles. If bubbles are present, hold the syringe straight up and tap

its side until the bubbles float to the top. Push them out with the plunger and withdraw the correct dose. · Remove the needle from the vial, being careful to not inject yourself. Caninsulin® cartridges

•The cartridge is designed to be used only with VetPen[™]. Follow the detailed instructions for use provided in the leaflet.

Giving the injection:

Client information sheet

 Injections should be given just under the skin (subcutaneously) 2-5 cm (3/4-2 inches) from the midline of the back (middle of your pet's back running from tail to head), varying from just behind the shoulder blade to slightly in front of the hipbone.

• The injection site should be alternated between your pet's left and right side.

· Using your free hand, pinch up a fold of skin and insert the needle into the center of the fold as instructed by your veterinarian. If using a syringe, push the plunger in as far as it will go. With the VetPen[™], push the release button towards the pen needle and hold it in place until the start line on the dose selector returns to the arrow on the insulin pen body, then wait a minimum of 5 seconds.

• Pull the needle out being careful to not inject yourself.

• Dispose of the syringe in an appropriate manner (sharps/biohazard disposal).

What are the possible side effects that may occur during Caninsulin® therapy?

The most common side effect experienced with Caninsulin® therapy is hypoglycemia (low blood sugar). Hypoglycemia can be caused by:

- Giving too much insulin · Missing or delaying food
- · Change in food, diet, or amount fed
- Change (increase) in exercise
- Infection or illness
- · Change in the body's need for insulin

· Diseases of the adrenal, pituitary, or thyroid gland, or progression of liver or kidney disease

· Interaction with other drugs (such as progestogen or glucocorticoids) Signs of hypoglycemia may occur suddenly and can include:

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

What do I do in case my pet shows signs of hypoglycemia? If your pet is unconscious or having a seizure, this is a medical emergency. Take your pet to your veterinarian immediately.

• If your pet is conscious, rub approximately 1 tablespoon of corn syrup or honey on your pet's gums. When it is able to swallow, give corn syrup or honey by mouth until your pet is alert enough to eat. Feed its usual meal and contact your veterinarian.

Other side effects that can be seen include loss of effectiveness and local or systemic allergic reactions. It is important to contact your veterinarian immediately if you think your pet has a medical problem or side effect from Caninsulin® therapy. In particular, please contact your veterinarian if your pet shows any of the following:

· Excessive water consumption for more than 3 days

· Excess urination (including need to urinate at night for a pet that usually sleeps through the night or inappropriate urination in the house)

- Reduced or loss of appetite
- Weakness, seizures, or severe mental depression
- · Behavioral change, muscle twitching, or anxiety
- · Constipation, vomiting, or diarrhea

· Signs of a bladder infection (small, frequent urinations, straining, blood in the urine)

· Swelling of the head or neck

What else can I do to keep my pet's blood sugar stable?

 Your pet's diet should be consistent and appropriate. A nutritionally complete, dry or canned pet food should be fed in consistent amounts at the same times each day or, at the discretion of your veterinarian, be available continuously.

• "Treats" and changes in diet should generally be avoided unless recommended by your veterinarian.

 Your veterinarian will advise you on how much and when to feed your pet based on the response to Caninsulin®.

· Your pet's exercise should remain consistent. Consult with your veterinarian if you expect a major change in activity.

· Develop a schedule with your veterinarian for regular evaluations of your pet's diabetes.

Can Caninsulin® be used with other medications?

Progestogen (such as megestrol) and glucocorticoids (such as cortisone, prednisone, dexamethasone, triamcinolone) should be avoided during Caninsulin® therapy. Progestogen, glucocorticoids, and certain endocrine diseases may counter the effect of insulin. Other medications may also interfere with your pet's response to insulin.

Tell your veterinarian about all the medicines you have given your pet in the past, and any medicines that you are planning to give with Caninsulin®. This should include other medicines that you can get without a prescription. Your veterinarian may want to check that all of your pet's medications can be given together.

What do I do in case my pet receives more than the prescribed amount of Caninsulin®?

If your pet is given too much Caninsulin®, severe (life-threatening) hypoglycemia (low blood sugar) can result. Contact your veterinarian immediately. If your veterinarian is not available, seek other veterinary advice at once. Your pet may need to be hospitalized for observation or treatment.

What do I do if my pet receives less than the prescribed dose, or I miss an injection?

· A missed or inadequate dose may cause temporary recurrence of signs (such as excess thirst and urination) but is not life-threatening. · Contact your veterinarian as soon as possible for advice on your pet's

next dose.

• If you cannot reach your veterinarian and your pet is eating and acting normal, give your pet the usual dose at the next regularly scheduled injection time.

How do I store Caninsulin®?

Caninsulin® should be stored in an upright position under refrigeration (2-8 degrees Celsius). Do not freeze. Protect from light. After the first dose is removed, the contents should be used within 6 weeks (vials) or 28 days (cartridges) and stored below 25 °C.

What else should I know about Caninsulin®?

This sheet provides a summary of information about Caninsulin®. If you have any questions or concerns about Caninsulin®, talk to your veterinarian.

It is important that your veterinarian periodically evaluate your pet's response to Caninsulin® at regular checkups that include blood glucose monitoring. Your veterinarian will best determine if your pet is responding as expected.

Additional information can be found at www.Caninsulin..ca

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