

GLUCOSE CURVE WORKSHEET



Date: _____ Pet Owner's name: _____

Pet's Name: _____

Age: _____ Sex: _____ Weight: _____ Spayed/Neutered (please select one): Yes No

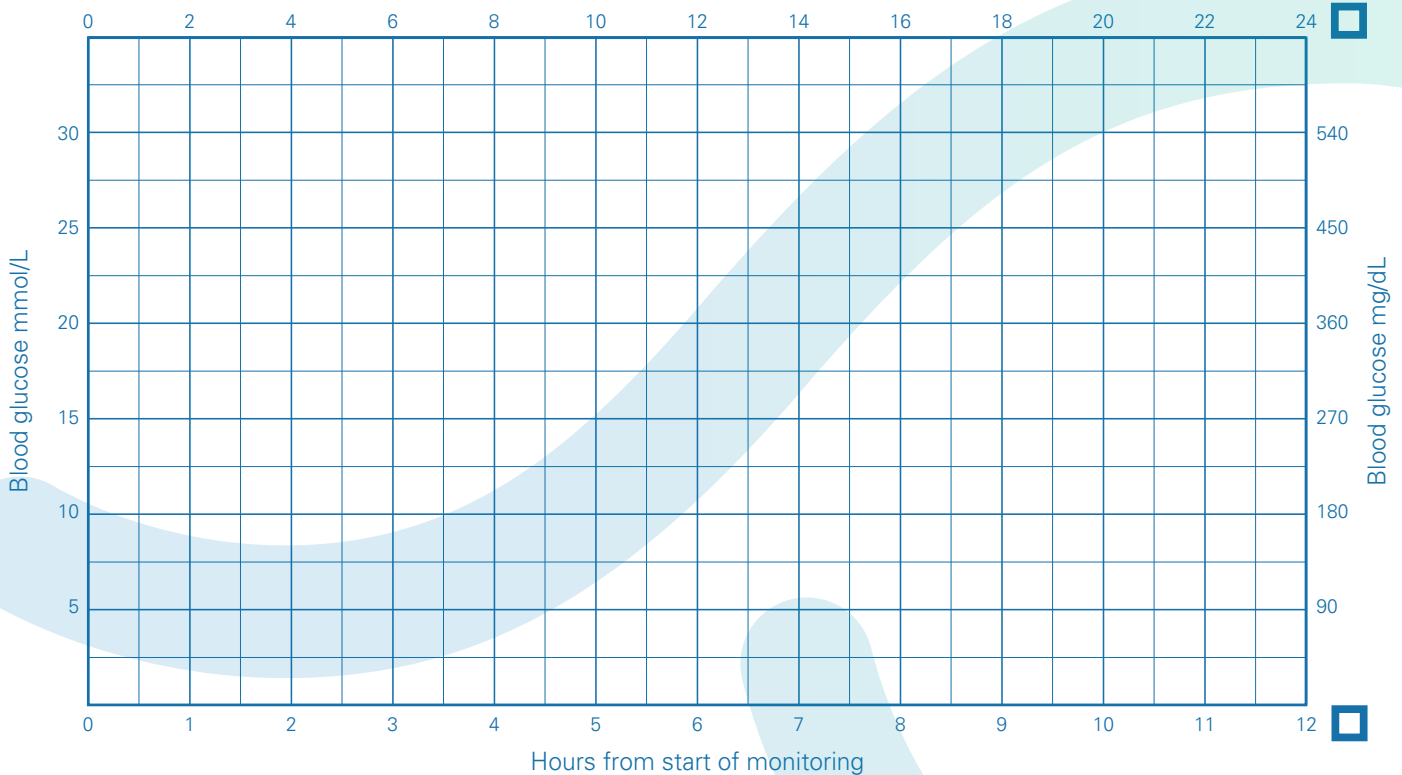
Breed: _____ Feeding time: _____

Body condition (please select one)*: 1 2 3 4 5

*1 = very thin, 2 = underweight, 3 = ideal weight, 4 = overweight, 5 = obese (score out of 5)

Please record time of injection(s) on the chart

Please select timescale used



Units of Caninsulin® Administered: _____ IU Time Glucose Curve started: _____ a.m. _____ p.m.

Time of Insulin administration: _____ a.m. _____ p.m. Time fed: _____ a.m. _____ p.m.

Comments: _____

Do not inject intravenously. Caninsulin® is not to be administered to hypoglycemic or anorexic dogs or cats. Dogs and cats known to have a systemic allergy to pork or pork products should not be treated with Caninsulin. KEEP OUT OF THE REACH OF CHILDREN. See package insert for full information regarding contraindications, warnings, monitoring and dose adjustment.

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Caninsulin®

Merck Animal Health

PORCINE INSULIN ZINC INJECTION (Mfr. Std.)

STERILE SUSPENSION, 40 I.U./ML

DIN 02052474, DIN 02416239

FOR VETERINARY USE ONLY

DESCRIPTION: Caninsulin is an intermediate-acting insulin. Each mL contains highly purified porcine insulin 40 IU (Ph. Eur.) consisting of 35% amorphous zinc insulin and 65% crystalline zinc insulin ("Lente" type). Non medicinal ingredients: (per mL): zinc chloride 0.08 mg, sodium acetate trihydrate 1.36 mg, sodium chloride 7.0 mg and methyl parahydroxybenzoate 0.1% (as preservative).

INDICATIONS: For the control of hyperglycemia associated with diabetes mellitus in dogs and cats.

DOSAGE AND ADMINISTRATION: The starting dose is calculated based on the dog's or cat's body weight as directed in the Table below. Dose-titration is necessary to meet the treatment needs of each individual animal. After a period of acclimatization, a blood glucose curve should be determined and the dose adjusted to achieve satisfactory long term control (see Monitoring and Dose Adjustment section below).

RECOMMENDED STARTING DOSES: Dogs: 0.5 I.U. per kg of body weight once daily, rounded down to the lowest entire number of units. Some examples are given in the table below.

Cats: 0.25 - 0.5 I.U. per kg of body weight, for a maximum of 2 I.U. per dose, based on blood glucose concentration at diagnosis, as presented in the Table below. Cats require twice daily administration.

Dogs	
Body Weight	Starting Dose
5 kg	2 I.U. once daily
10 kg	5 I.U. once daily
15 kg	7 I.U. once daily
20 kg	10 I.U. once daily

Cats	
Blood Glucose Concentration	Starting Dose
< 20 mmol/L or < 3.6 g/L (360 mg/dL)	0.25 I.U./kg twice daily
≥ 20 mmol/L or ≥ 3.6 g/L (360 mg/dL)	0.5 I.U./kg twice daily

Subsequent adjustment to establish the maintenance dose should be made by increasing or decreasing the dose according to clinical signs and serial blood glucose measurements (see Monitoring and Dose Adjustment below).

ADMINISTRATION: With vials, the use of U-40 insulin syringes is strongly recommended to ensure accurate dosing. The cartridge is designed to be used **only** with VetPen® and 29 G/12 mm single use needles. VetPen® is accompanied by a package leaflet with detailed instructions for use to be followed.

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.

The contents should be used within 6 weeks (vials) or 28 days (cartridges) and stored below 25°C after the first dose is removed.

Inject subcutaneously 2 to 5 cm from the dorsal midline on alternating sides, varying from behind the scapula to the mid-lumbar region. Veterinarians should instruct pet owners on proper storage and handling, show them how to draw the insulin from the bottle, and instruct them on how to administer Caninsulin.

DIET: A nutritionally complete commercial dry or canned pet food should be fed in consistent amounts and at consistent times each day, according to the veterinarian's recommendations. Animals receiving Caninsulin injections once daily should be fed 1/2 to 2/3 of their caloric requirement at the time of injection and 1/2 to 1/3 of their requirement approximately 8 to 10 hours later, depending on the client's schedule. Animals receiving Caninsulin injections twice daily should be fed 1/2 of their caloric requirement at the time of each injection.

MONITORING AND DOSE ADJUSTMENT: Since the times to the peaks and the duration of insulin activity from Caninsulin will vary among animals, the dose should be adjusted based on the measurement of blood glucose levels. They should be determined 2 to 4 hours after each injection for the first 2 days to assure the animal is not becoming dangerously hypoglycemic (blood glucose < 80 mg/dL, 4.4 mmol/L). The animal should then be allowed to acclimate to this treatment 4 to 5 days before determining the glucose curve and adjusting the dose. A glucose curve should be obtained by administering Caninsulin, feeding the animal as described under the DIET section, and measuring blood glucose every 1 to 2 hours for 24 hours. In dogs and cats, the dose should then be adjusted by 10 percent per day until the lowest blood glucose is approaching normal glycemia or between 4.4 - 6.6 mmol/L (80-120 mg/dL). While adjusting the dose, the blood glucose should be measured 2 or 3 times daily, at the times when it is expected to be lowest as determined by the glucose curve, and just before the next dose is to be given.

Once the dose that will reduce blood glucose to 4.4 - 6.6 mmol/L (80-120 mg/dL), is established, the blood glucose curve may need to be repeated to accurately determine the peaks and duration of activity resulting from this dose. In dogs administered Caninsulin once daily,

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if the duration of insulin action is less than 16 hours (blood glucose is reduced to 4.4 - 6.6 mmol/L (80-120 mg/dL), but increases to 13.9 mmol/L (250 mg/dL) less than 16 hours after administration), Caninsulin may be given twice daily at 12 hour intervals. Initially, the 2 doses should be equal and each dose should be 25% less than the dose that reduced the blood glucose to between 4.4 - 6.6 mmol/L (80-120 mg/dL), when Caninsulin was given once daily. The doses should then be adjusted as described above. The dose given in the evening may be less than the dose given in the morning, if control of hyperglycemia is improved by doing so.

As an alternative, the insulin dose can be adjusted, based on daily measurement of morning urine glucose levels by the client. Although this is an acceptable method, it is not recommended as the sole criterion upon which to adjust the dose, because factors other than insulin dose can affect urine glucose concentration. In dogs and cats, the aim should be to manage the diabetic animals so as to reduce or eliminate the clinical signs of diabetes mellitus whilst minimizing the occurrence of hypoglycemia; obtain normal blood glucose concentrations between 5-14 mmol/l (100-250 mg/dL) in the dog and 5-17 mmol/l (100-300 mg/dL) in the cat; attain and/or maintain normal bodyweight, and to minimize and/or eliminate polydipsia, polyuria, and polyphagia (if present). In the cat, since clinical diabetic remission may be possible, it is important to monitor for signs of hypoglycemia.

Once adequate control is achieved, the animal should be re-examined in one week. If control remains adequate at that time, regular examinations should be scheduled at 3 to 4 month intervals, or whenever the client notes one or more of the following: Polydipsia (daily water consumption > 70 ml per kg of body weight for 3 or more days); Polyuria; Inappetance or anorexia, polyphagia; Loss of body weight or condition; Weakness and/or dizziness.

If control is found to be inadequate, the dose or doses should be re-adjusted as described above. The blood glucose curve may also need to be repeated.

OVERDOSE: If the dog or cat shows signs of hypoglycemia: weakness, confusion, dizziness or seizures, the animal should be re-examined immediately. In mild cases offer the animal its usual food. More serious symptoms can be treated with an oral dextrose solution or corn syrup rubbed on the oral mucosa or an intravenous injection of a 50% dextrose solution.

CONTRAINDICATIONS: Do not inject intravenously. Caninsulin is not to be administered to hypoglycemic or anorexic dogs or cats. Dogs and cats known to have a systemic allergy to pork or pork products should not be treated with Caninsulin.

CAUTIONS: Animals which present with severe ketoacidosis, anorexia and/or vomiting should be stabilized with short acting insulin before beginning treatment with Caninsulin. Stress and irregular extra exercise must be avoided. Diabetic control is best achieved in spayed bitches and queens. Therefore, intact diabetic females should be spayed as soon as they are stable enough to withstand the procedure. The use of progestogens (estrus inhibitors) and long acting glucocorticoids in patients suffering from diabetes mellitus should be avoided. The concurrent administration of drugs known to lower blood glucose such as oral hypoglycemic drugs is not recommended. Depending on the etiology of the diabetes mellitus insulin therapy alone may not be sufficient and additional diagnostics and treatment may be required.

WARNINGS: 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. **KEEP OUT OF THE REACH OF CHILDREN.**

ADVERSE REACTIONS: Local injection site reactions have been reported rarely in dogs and very rarely in cats. These reactions are usually mild and reversible. In very rare cases, allergic reactions to porcine insulin have been reported.

Although all adverse reactions are not reported, the following adverse reaction information is based on voluntary post-approval drug experience reporting. It is generally recognized that this method of reporting results in significant under-reporting of adverse drug reactions.

It should be noted that suspected adverse reactions listed here reflect reporting and not causality. The following adverse reactions are listed in decreasing order of frequency.

Adverse events in **cats** include: lack of effectiveness/dysregulation, decreased appetite/anorexia, vomiting, lethargy, death, injection site reaction, hypoglycemia, ataxia, diarrhea, seizures, and polyuria/polydipsia.

Adverse events in **dogs** include: lack of effectiveness/dysregulation, lethargy, allergic or skin reaction, vomiting, hypoglycemia, injection site reaction, ataxia, decreased appetite/anorexia, seizures, and diarrhea.

PHARMACOLOGY: Canine and feline diabetes mellitus is an endocrinopathy resulting from relative or absolute insulin deficiency. Insulin deficiency impairs cellular uptake of glucose and promotes hepatic gluconeogenesis. When the renal threshold for glucose is exceeded, glucosuria results, along with osmotic diuresis leading to polyuria and polydipsia. Unmanaged diabetes results in ketosis, ketoacidosis, and if left untreated, acidosis, coma and death. Most forms of canine or feline diabetes can be successfully managed by controlling hyperglycemia with regular administration of exogenous insulin and dietary manipulation. The amino acid structure of porcine insulin is identical to the amino acid structure of canine insulin and 3 amino acids different from feline insulin.

In dogs, the amorphous fraction of Caninsulin gives a peak of activity at approximately 3 hours and a duration of action of approximately 8 hours. The crystalline fraction gives a peak of activity at 7 to 12 hours and a duration of activity of approximately 24 hours. In cats, Caninsulin has a peak of activity at approximately 4-6 hours post-administration and a duration of activity of 8 to 12 hours. Accordingly, Caninsulin should be administered once daily in dogs and twice daily in cats. However, the times to the peaks and durations of insulin activity from Caninsulin will vary among individual animals.

STORAGE: Refrigerate at 2-8°C. Store in an upright position, in the dark. Do not freeze.

HOW SUPPLIED: Box of 10 x 2.5 mL vials; Box of 1 x 10 mL vial; Box of 10 x 2.7 mL cartridges (for use only with VetPen® insulin delivery pen)

For further information please refer to the Client Information Sheet which can be found at www.caninsulin.ca

Intervet Canada Corp., Kirkland, QC, Canada H9H 4M7

1 866 683-7838

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