

WITH YOU AND YOUR DOG FOR LIFE



DIABETES DIARY

Dog's name

Birth Date

Sex

Age

Coat Color

Breed



caninsulin[®]

with you for life



MSD

Animal Health

PROFILE

Your name

Telephone

Email

Vet's name

Telephone

Email

Weight

Spay/Neuter (Yes/No)

Medical history

Medications

Your Address

Vet's Address

Clinical signs

Allergies

Other comments

DIABETES MANAGEMENT

Your dog's insulin needs can be restored by daily injections of Caninsulin®. This is easy, takes very little time and is not painful.

Caninsulin should be injected under the skin (subcutaneously) using U40 insulin syringes. The first Caninsulin injection is normally given in the morning during or close to your dog's morning meal.

If your dog is not eating normally, do not administer an insulin injection until you have talked to your veterinarian.

Injection tips

- If necessary, ask someone to hold your dog prior to injecting Caninsulin.
- Ideally, the site of injection should be rotated from behind shoulder blade to slightly in front of hip bone and alternated between left and right sides. Ask your veterinarian for advice.
- Feed your dog before, during or after the injection, based on your vet's advice.

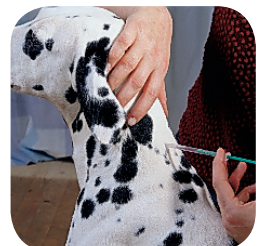
Giving an injection with a U40 insulin syringe*

1. Caninsulin should be stored upright in the fridge. Do not freeze.
2. Remove the Caninsulin from the fridge and shake the vial thoroughly to obtain a homogeneous, uniformly milky suspension.



* See package insert for full information.

3. Carefully remove the cap from the U40 insulin syringe needle.
4. Insert the needle into the Caninsulin vial.
5. Draw up the correct dose of Caninsulin into the U40 insulin syringe.
6. Before injection, remove air bubbles by tapping the U40 insulin syringe with your finger and then pressing the plunger very gently.
7. Draw a small area of your dog's skin gently upwards and make a small hollow with your index finger.
8. Place the needle in this hollow and push it gently through the skin and then release the skin.
9. Depress the syringe plunger steadily until all of the insulin dose has been injected.



IMPORTANT:

Only use a U40 insulin syringe with Caninsulin.

DIABETES MANAGEMENT

Managing your dog's diet and exercise

The daily dose of Caninsulin is adjusted to match your dog's daily energy requirements. This includes energy intake from food and energy expended during exercise or other activity.

Discuss the most suitable diet for your dog with your veterinarian. If your dog needs to lose weight, your veterinarian will advise you on a suitable diet as well as frequency and size of meals. Keep all meals and snacks the same to avoid fluctuations in insulin requirements. However tempting, never give your dog any titbits or treats unless these have been approved as suitable by your veterinarian - this will require the cooperation of your family and friends too!

Regular exercise and other activity is an important part of every dog's life and this is even more important for diabetic dogs. Variable exercise or sudden changes in activity mean that energy expenditure (e.g. an extra long walk, excitement about visitors, etc.) varies and this can lead to changes in insulin requirements.

Dogs

Diabetic dogs are usually fed at least twice daily – once to ensure that they are feeling well and able to eat and once to make sure they have enough glucose available to match the insulin they have been given - this second meal is given around 8 hours after Caninsulin injection but the timing will differ from dog to dog.



BE PREPARED FOR HYPOGLYCEMIA

One of the most important complications seen in diabetic dogs on insulin treatment is lower than normal blood sugar (hypoglycemia). Situations where this may occur include:

- Giving too much insulin
- Missing or delaying food
- Change in diet or amount fed
- Infection or illness
- Variation in amount and intensity of exercise
- Interaction with other drugs
- Presence of other chronic diseases

It is important that you know what to do if hypoglycemia (low blood glucose) occurs.

Watch out for the signs:

- Restlessness
- Trembling or shivering
- Unusual movements or behaviour
- Loss of consciousness (coma) and unusual quietness or sleepiness

Glucose solution

- Glucose solution can be made from glucose powder which can be mixed with tap water.
- Give one gram of glucose per kilogram body weight.

What to do if you see these signs:

1. Provide food immediately
2. If your dog refuses to eat or cannot eat, administer a glucose source as quickly as possible. Administer the glucose solution very carefully into the cheek pouch using a syringe and make sure the solution does not go down the wrong way. Only do this if you are sure that your dog can swallow.

IF YOUR DOG IS UNCONSCIOUS OR HAVING A SEIZURE: CONTACT YOUR VETERINARIAN THIS IS AN EMERGENCY!

What you can do:

1. Treat your dog immediately - do not delay treatment
2. If your dog is unconscious or unable to swallow, rub the glucose solution onto the gums and especially under the tongue. Watch your fingers to avoid an accidental bite
3. Glucose is absorbed very quickly (1-2 minutes) and your dog should be responsive
4. Do not pour solution directly into dog's mouth - there is a risk it could be inhaled into the lungs
5. Once your dog has responded and is sitting up, feed a small amount of his/her usual food
6. When your dog is stabilized, immediately take him/her to your veterinarian for evaluation

MONITORING TREATMENT

Insulin is used in diabetics to help balance blood sugar, along with managing energy intake (food) and energy expenditure (regular exercise). Although your dog may have been stable for a long time, changes in dose may suddenly be required.

This is why it is important to continue to monitor and record your dog's progress - even after months or years of treatment:

- Ensure you administer the prescribed dose of insulin daily and do not increase the insulin dose unless your veterinarian advises you to do so
- Monitor and record water and food consumption
- Monitor and record urine production (e.g. how often your dog needs to go out)
- Weigh your dog regularly (e.g. once per month) and record your dog's weight
- Monitor and record urine glucose and/or ketones and/or blood glucose, if advised to do so by your veterinarian

Caninsulin Dosage

Starting dose

IU

Dosing frequency

time/day

Diet

Name of food:

Meal 1

Food

Meal 2

Food

If your dog is not eating, contact your veterinarian. Don't forget to share your monitoring records - these include important information on when your dog was doing well and the insulin dose it was on at that time.

Exercise

Notes

PRODUCT INFORMATION

NAME OF THE VETERINARY MEDICINAL PRODUCT

Caninsulin 40 IU/ml Suspension for Injection

QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:

Insulin 40 IU

PHARMACEUTICAL FORM

A white to almost white suspension for injection.

CLINICAL PARTICULARS

Target Species

Dogs and cats

Indications for use, specifying the target species

Caninsulin is indicated in cases of diabetes mellitus (insulin deficiency) in dogs and cats, where the required blood glucose levels are achieved by using an individually adjusted dose of Caninsulin.

Contraindications

Caninsulin is not intended for the treatment of animals with severe acute diabetes presenting in a ketoacidotic state. Caninsulin must not be administered by the intravenous route.

Special warnings

None.

Special precautions for use

Special precautions for use in animals

It is important to establish a strict feeding schedule in consultation with the owner which will include a minimum of fluctuations and changes. Clinical signs of hunger, increased anxiety, unstable locomotion, muscle twitching, stumbling or sinking in the rear legs and disorientation in the animal indicate hypoglycaemia and require immediate administration of glucose solution or food to restore blood glucose concentrations to normal. The product must be administered with specific U-40 sterile single-use syringes (vial).

Special precautions to be taken by the person administering the veterinary medicinal product to animals

Accidental self-injection can provoke clinical signs of hypoglycaemia, which should be treated by oral administration of glucose.

In case of accidental self-injection seek medical advice immediately and show the package insert or label to the physician

Adverse reactions (frequency and seriousness)

Very rare cases of local adverse reactions associated with administration of porcine insulin have been reported in dogs and cats. These reactions are usually mild and reversible. In extreme rare cases, allergic reactions to porcine insulin have been reported.

Use during pregnancy, lactation or lay

The use of Caninsulin is not contra-indicated during pregnancy or lactation but requires close veterinary supervision to account for changes in metabolic requirements during this period.

Interaction with other medicinal products and other forms of interactions

Changes in insulin requirements may result from administration of substances which alter glucose tolerance such as corticosteroids and progestagens. Monitoring of glucose levels should be used to adjust dose accordingly. Similarly, changes in diet or exercise routines may alter insulin requirements.

Amounts to be administered and administration route

Caninsulin should be administered once or twice daily, as appropriate, by subcutaneous injection. 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. Agglomerates can form in insulin suspensions. Do not use the product if visible agglomerates persist after shaking thoroughly.

When using vials:

A 40 IU/ml insulin syringe should be used.

When using product in cartridges:

The cartridge is designed to be used with VetPen. VetPen is accompanied by package leaflet with detailed instruction for use to be followed.

Stabilisation phase

Dog: Insulin therapy is initiated with the starting dose of 0.5 IU/kg bodyweight once daily, rounded down to the lowest entire number of units. Some examples are given in the following table.

Dog body weight Starting dose per dog

5kg	2IU once daily
10kg	5IU once daily
15kg	7IU once daily
20kg	10IU once daily

Subsequent adjustment to establish the maintenance dose should be made by increasing or decreasing the daily dose by approximately 10% according to the evolution of the diabetes clinical signs and to the results of serial blood glucose measurement. Alterations in dose should not normally be made more frequently than every 3 to 7 days. In some dogs, the duration of insulin action may require treatment to be administered twice daily. In such cases, the dose per injection must be decreased by 25% so that the total daily dose is less than doubled.

For example, for a 10 kg dog receiving 5 IU once daily, the new dose (rounded down to the nearest whole unit) would be 3 IU per injection initially. The two daily doses should be administered at 12h intervals. Further dose adjustments should be made progressively as previously explained.

To achieve a balance between the generation of glucose and the effect of the product, feeding should be synchronized with the treatment and the daily ration divided into two meals. The composition and quantity of the daily food intake should be constant. In dogs treated once daily, the second meal is usually fed at the time of peak insulin effect.

In dogs treated twice daily, feeding coincides with Caninsulin administration. Each meal should be fed at the same time each day.

Cat: The initial dose is 1 IU or 2 IU/kg per injection based on the baseline blood glucose concentration, as presented in the following table.

Cats require twice daily administration.

Cat blood glucose concentration	Starting dose per cat
<20 mmol/l or <3.6 g/l (<360 mg/dl)	1 IU twice daily
≥20 mmol/l or ≥ 3.6 g/l (≥360 mg/dl)	2 IU twice daily

The composition and quantity of the daily food intake should be constant.

Subsequent adjustment to establish the maintenance dose should be made by increasing or decreasing the daily dose according to the results of serial blood glucose measurement. Alterations in dose should not normally be made more frequently than every week. Increments of 1 IU per injection are recommended. Ideally, no more than 2 IU should be administered per injection in the first three weeks of treatment. Due to the day-to-day variation in the blood glucose response, and the variations in insulin responsiveness that are seen with time, larger or more frequent increases in dose are not recommended.

Maintenance phase in dogs and cats

Once the maintenance dose has been reached and the animal is stabilised, a long-term management programme needs to be established. The aim should be to manage the animal in such a way as to minimise the variations in its insulin requirement. This includes clinical monitoring to detect under or overdosage of insulin and adjustment of dose if required. Careful stabilisation and monitoring will help to limit the chronic problems associated with diabetes, including cataracts (dogs), fatty liver (dogs and cats), etc.

Follow up examinations should be performed every 2-4 months (or more often if there are problems) to monitor the animal's health, the owner's records, urine glucose and biochemical parameters (like blood glucose and/or fructosamine concentration). Adjustments to the insulin dose should be made based on interpretation of the clinical signs supported by the laboratory results.

Overdose

Overdose of insulin results in clinical signs of hypoglycaemia. Owners and veterinarians should be aware of the Somogyi over-swing which is a physiological response to hypoglycaemia. As a partial hypoglycaemia begins to develop a hormonal response is triggered which results in the release of glucose from hepatic glycogen stores. This results in rebound hyperglycaemia, which may also manifest as glucosuria for part of the 24-hour cycle. There is a danger that the Somogyi over-swing will be interpreted as a requirement for an increase in the insulin dose rather than a decrease. This situation can progress to an overdose so large as to cause clinical hypoglycaemic effects.

Pharmacodynamic properties

Insulin facilitates the uptake of glucose by cells and activates intracellular enzymes involved in the use and storage of glucose, amino acids and fatty acids. Insulin also inhibits catabolic processes such as proteolysis, gluconeogenesis and lipolysis. Diabetes mellitus is characterised by an absolute or relative insulin deficiency leading to persistent hyperglycaemia, and monitoring blood glucose concentration enables assessment of the overall effect of the administered insulin. In diabetic dogs, the action of Caninsulin on blood glucose concentrations, following subcutaneous administration, peaks at about 6-8 hours post-injection and lasts for about 14 to 24 hours. In diabetic cats, the action of Caninsulin on blood glucose concentrations after subcutaneous administration peaks at about 4-6 hours and last for about 8 to 12 hours post-injection.

Pharmacokinetic particulars

Caninsulin is an insulin of intermediate duration of action that contains both amorphous and crystalline insulin in a 3.5:6.5 ratio. In diabetic dogs, the peak plasma concentration of insulin occurs at about 2-6 hours after subcutaneous injection, and insulin remains above pre-injection level for about 14 to 24 hours. In diabetic cats, the peak plasma concentration of insulin occurs at about 1.5 hours after subcutaneous injection and insulin remains above pre-injection level for about 5 to 12 hours.

Incompatibilities

None known.

Shelf-life

Shelf life: 2 years. Vials: following withdrawal of the first dose, use the product within 42 days. Cartridges: following withdrawal of the first dose, use the product within 28 days.

Special precautions for storage

Store upright and refrigerated between +2 C and +8 C.

Do not freeze

Protect from light.

After first opening, store below 25°C and away from direct heat or direct light.

Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

Any unused product or waste material should be disposed of in accordance with national requirements.

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