

RESTRICTED VETERINARY MEDICINE

Keep out of reach of children

FOR ANIMAL TREATMENT ONLY

CANINSULIN[®]

Insulin for Dogs and Cats

DESCRIPTION

Caninsulin is an aqueous suspension of 40 IU per mL of highly purified porcine insulin, 30% as amorphous zinc insulin and 70% as crystalline zinc insulin.

PRESENTATION

Caninsulin is available in two different presentations, either a vial or a cartridge.

Vial: 1 x 10mL vial in a carton for use in large diabetic dogs. Use with a 40 IU per mL syringe.

Cartridge: 2.7mL cartridge supplied in a carton. The cartridge is only to be used with the VetPen[™] (Veterinary Automatic Insulin Delivery Pen).

The VetPen has been specially developed to enable dosing of smaller volumes of Caninsulin and is available in two sizes:

- VetPen 8 – delivers 0.5 to 8 IU of insulin per injection in 0.5 IU increments for use in diabetic cats and small dogs.
- VetPen 16 –delivers 1 to 16 IU of insulin per injection in 1.0 IU increments, for use in small to medium-sized diabetic dogs.

MODE OF ACTION

Caninsulin is an insulin product with intermediate action. It contains porcine insulin, which is structurally identical to canine insulin. In cases of insulin deficiency and/or decreased insulin sensitivity, the required blood levels can be achieved by using an individually adjusted dose of Caninsulin.

The action of Caninsulin on blood glucose concentrations, following subcutaneous administration, peaks in diabetic dogs at approximately 6-8 hours post-injection and lasts for about 14 - 24 hours; in diabetic cats, it peaks at approximately 4 – 6 hours post-injection and lasts for about 8 -12 hours.

INDICATIONS

Treatment of diabetes mellitus in dogs and cats.

CONTRAINDICATIONS

- Hypoglycaemia.
- Caninsulin is not intended for the initial treatment of animals with severe acute diabetes mellitus that are presented in a ketoacidotic state.
- Must NOT be administered by intravenous route.
- The use of progestogens (oestrus inhibitors) should be avoided in animals suffering from diabetes mellitus. In entire bitches, ovariohysterectomy may have to be considered.
- Care must be taken with the use of glucocorticosteroids.
- Stress and irregular exercise must be avoided.

DIRECTION FOR USE

Ensure correct storage of product (see STORAGE below).

Caninsulin should be administered by subcutaneous injection. Alternate the site of injection daily.

Caninsulin requires thorough mixing to obtain a uniform, milky solution prior to use.

VIALS:

Shake the vial thoroughly until a uniform milky solution is obtained. Foam on the surface formed during shaking should be allowed to disperse before use. If necessary, once the foam disperses, the vial can be gently inverted to maintain the milky solution prior to use. Agglomerates can form in the insulin suspensions. **Do not use the product if visible agglomerates persist after shaking thoroughly.**

The dose depends on the degree of deficit in the animal's own insulin production and is therefore different in each case. As a consequence, a dose-titration phase will always be necessary in order to tailor the treatment to each individual animal.

A single daily injection of Caninsulin may be sufficient to reduce the blood glucose in some diabetic dogs. Other dogs may require twice-daily injections as the duration of action of the insulin may vary within an individual. In diabetic cats, it is necessary to administer Caninsulin twice-daily.

DOSAGE AND ADMINISTRATION

For large dogs:

Use Caninsulin 10mL vials. It is **strongly recommended** that a 40 IU per mL syringe is used.

For cats and small to medium-sized dogs:

A Caninsulin cartridge is used with the VetPen to enable dosing of smaller volumes. The VetPen is accompanied by a leaflet which provides detailed instructions of use.

- For cats and small dogs - Use the Caninsulin cartridge with **VetPen 8**
- For small to medium-sized dogs - Use the Caninsulin cartridge with **VetPen 16**

STABILISATION PHASE

Dog: The initial **STARTING** dose of Caninsulin is **0.5 IU/kg** body weight **once-daily** (rounded down to the nearest whole unit).

Example (once-daily):

Dog Bodyweight	Starting dose per dog
5 kg	2 IU once-daily
10 kg	5 IU once-daily
15 kg	7 IU once-daily
20 kg	10 IU once-daily

Subsequent adjustment **to establish the maintenance dose** should be made by increasing or decreasing the daily dose by approximately 10% according to clinical signs and 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% and this dose given twice-daily.

For example, with a 10kg dog receiving 5 IU once-daily, the new dose (5 minus 25%, rounded down to the nearest whole unit) would be 3 IU per injection initially. The two daily doses **must** be administered at 12 hour intervals.

Example (twice-daily):

Dog Bodyweight	Starting dose per dog
5 kg	1 IU twice-daily
10 kg	3 IU twice-daily
15 kg	5 IU twice-daily
20 kg	7 IU twice-daily

Further dose adjustments should be made progressively (in 10% increments) as previously explained.

To achieve a balance between the generation of glucose and the effect of Caninsulin, feeding must be synchronised 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 first meal is given at the time of Caninsulin administration and the second meal is usually fed at the time of peak insulin effect (i.e. 6 - 8 hours post-injection). In dogs treated twice-daily, feeding coincides with Caninsulin administration. Each meal should be fed at the same time each day.

Cat: Cats require **TWICE-DAILY** Caninsulin administration.

The initial **STARTING** dose depends on the weight and the fasting blood glucose of the diabetic cat (see table below for guidance). However, a **maximum of 2 IU** should only be given twice-daily in the **first 3 weeks** e.g. an 8kg cat calculated to require 4IU twice-daily should initially receive 2 IU twice-daily for the first 3 weeks.

Cat Blood Glucose Concentration	Starting dose per cat twice-daily
<20 mmol/L	0.25 IU/kg twice-daily
≥20 mmol/L	0.5 IU/kg twice-daily

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 measurements. Alterations in dose should not normally be made more frequently than every week. Increments of 1 IU per injection are recommended. 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.

The composition and quantity of the daily food intake should be constant. Cats that usually “graze” may be allowed to eat ad lib.

MAINTENANCE PHASE- 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 over-dosage 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 and biochemical parameters like blood glucose and/or fructosamine concentrations. Adjustments to the insulin dose should be based on clinical signs supported by the laboratory results.

ADVICE ON CORRECT ADMINISTRATION

Administration of Caninsulin must be carried out by an adult responsible for the welfare of the animal. The ability of owners to recognise the clinical signs of hypo or hyper glycaemia, and to respond appropriately, is important if control is achieved during maintenance therapy.

Polyuria (frequent urination), polydipsia (excessive water intake) and polyphagia (excessive food intake) in combination with weight loss, poor general condition, hair loss or abnormal coat and lethargy (marked apathy) are the most common clinical signs of hyperglycaemia and requires the administration of insulin or an adjustment to the insulin dose to restore blood glucose concentrations to within the normal range.

Insulin over-dosage results in signs of hypo-glycaemia. Signs of hunger, increasing anxiety, muscle twitching, stumbling, hind limb weakness or disorientation indicate progression of hypoglycaemia and requires immediate administration of glucose solution and/or food to restore blood glucose concentration.

Somogyi effect (rebound hyperglycaemia) is a response to an overdose of insulin sufficient to cause potentially fatal hypoglycaemia. As hypoglycaemia begins to develop, a hormonal counter-regulatory response is triggered which results in release of glucose from hepatic glycogen stores. This results in rebound hyperglycaemia which may also manifest as glycosuria for part of the 24 hour cycle. There is a danger that the Somogyi effect is interpreted as a requirement for increase in the insulin dose rather than a decrease. This can be avoided by basing decisions on serial blood glucose measurements rather than single point measurements.

ADVERSE EFFECTS

Hypoglycaemia may result from administration of excessive insulin. Oral glucose should be given immediately. 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 extremely rare cases, allergic reactions to porcine insulin have been reported.

HANDLING PRECAUTIONS

Care should be taken when administering this product. Accidental self-injection can provoke clinical signs of hypoglycaemia, which should be treated by oral administration of glucose. Seek medical advice immediately and show this leaflet or label to the doctor. In sensitised subjects, accidental administration can induce local or general allergic reactions. See Safety Data Sheet for further information. www.msd-animal-health.co.nz

STORAGE

Ensure correct storage of product. Incorrect storage may result in crystallisation (and agglomerate formation) of the active insulin.

VIALS:

Always store in an upright position. Store unopened vials between 2°C and 8°C. (Refrigerate).

DO NOT FREEZE. Protect from light. After first use, opened vials may be stored below 25°C. Discard any unused portion after 6 weeks.

ACVM Registration No. A7401. See www.foodsafety.govt.nz for registration conditions.

Registered to:

Schering-Plough Animal Health Ltd

33 Whakatiki St, Upper Hutt.

Phone: 0800 800 543

www.msd-animal-health.co.nz