caninsulin®
with you for life

THE FIRST

Veterinary Insulin Approved for Both Dogs and Cats

The first to offer a choice in administration:

- 10 mL vial
- 0.5 mL or 1.0 mL U40 insulin syringes

With Proven Efficacy and Reassuring Safety

- Reduces hyperglycemia and resolves clinical signs of diabetes in dogs[1]
- Reduces hyperglycemia, resolves clinical signs and can lead to remission in cats[2]

Over 25 Years of Worldwide Use in Dogs and Cats*

Go to www.caninsulin.com to find out more

Caninsulin® should not be used in dogs or cats known to have a systemic allergy to pork or pork products. Caninsulin® 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 Caninsulin® 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.

Please see other side for full prescribing information. *Caninsulin is known as Vetsulin® in the U.S.A.

References: 1. Monroe WE. et al. J Vet Intern Med. 2005; 19:675-682. 2. Martin, G. W. & Rand, J. S. Vet Rec. 2007.

MSD Animal Health

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 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/1 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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