PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Caninsulin vet. 40 IU/ml suspension for injection for dogs and cats

2. Composition

Active substance:
Each ml contains: 40 IU insulin porcine, containing 35% amorphous and 65% crystalline Zinc insulin.
White to almost white suspension for injection:

Excipient:
Each ml contains 1.0 mg methyl parahydroxybenzoate

3. Target species

Dogs and cats

4. Indications for use

Diabetes mellitus in dogs and cats

5. Contraindications

Do not use in case of hypoglycemia.
Do not use in cases of hypersensitivity to insulin porcine or to any of the excipients.

6. Special warnings

Special warnings:
In the female dog, clinical signs of diabetes can be caused by hormones (progestogens) during the heat cycle (metestrus) or therapeutic use (e.g., heat suppression).

In the cat, diabetic clinical remission is possible. The diagnosis may therefore need to be reconsidered and the treatment discontinued.

Special precautions for safe use in the target species:

What to consider when using this medicine?

When the dose is established, the level of glucose in the urine should be checked regularly. Test strips, which are easy to use, are available at the pharmacy.

It is important to establish a strict feeding schedule which will include a minimum of fluctuations and changes. This should be done in collaboration with the veterinarian. Irregular or excessive exercise should be avoided.

What to do in case of low blood glucose levels (hypoglycemia)? To restore the blood glucose level, in case the animal would show symptoms indicating high insulin levels, you should always have Dextrosol tablets (glucose tablets) at home, which you can immediately give to the animal.

Symptoms of low blood glucose are hunger, increasing shyness, uncoordinated movements, muscle spasms, unsteady movements and disorientation.

What to do with too high blood glucose levels (hyperglycemia)? Increased urination, increased thirst and increased hunger together with weight loss, poor general health, hair loss or poor coat and lethargy are the most common signs of hyperglycemia. The condition requires administration of insulin or adjusting the dose of insulin to restore blood glucose levels.

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

Accidental self-injection may cause clinical symptoms of low blood glucose (hypoglycemia), which should be treated with oral administration of glucose. In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician. Accidental medication may induce local or systemic allergic reactions in sensitive individuals.

Pregnancy and lactation:

Can be used during pregnancy or lactation in exceptional cases but this requires close veterinary supervision in order to maintain the correct dosage and feeding.

Interaction with other medicinal products and other forms of interaction:
The treatment effect may be affected if this medicinal product is administered together with some other medicinal products. The attending veterinarian must therefore be made aware of any such concomitant medication.

Overdose:
Insulin overdose results in signs of low blood glucose (hypoglycemia). If an insulin-treated dog or cat shows signs of hunger, increasing fear, unstable movements, muscle twitching, staggering gait and disorientation, the blood glucose level is too low, which requires immediate administration of glucose solution and feed, to restore blood glucose levels.
If the condition worsens or is repeated, a veterinarian should immediately be consulted.

Major incompatibilities:
In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

7. Adverse events

Dogs and cats

Rare (1 to 10 animals / 10,000 animals treated):	Hypoglycaemia
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Injection site reaction[1] Hypersensitivity reaction

[1] The reaction is usually mild and reversible.

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder <or the local representative of the marketing

authorisation holder> using the contact details at the end of this leaflet, or via your national reporting system: {national system details}

<to be completed nationally>

8. Dosage for each species, routes and method of administration

The dose is determined by a veterinarian who will adjust the dose individually for the dog or cat which will be treated.

Adjustment phase:

Dog:
Caninsulin vet. must be injected subcutaneously and must not be administered intravenously.
The dose depends on the degree of lack of insulin (insulin insufficiency). The dose is determined by a series of measurements of glucose levels in the blood and differs from case to case.

Insulin therapy is initiated with a starting dose of 0.5 IU/kg body weight once daily, rounded down to the lowest integer of units. See examples in the table below:

Dog body weight	Starting dose of Caninsulin vet. 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

The injection is administered subcutaneously once daily together with feeding. In some dogs, administration of insulin may be needed twice daily. It may therefore be necessary and in consultation with a veterinarian to divide the insulin dose into 2 injections daily. When the daily dose is divided the veterinarian may prescribe a higher total daily dose. The two daily doses should be administered at 12-hour intervals.

The daily feed ration shall be divided into two meals. The quality and quantity of the daily food intake should stay constant.

In dogs treated with insulin once daily, 1/3 of the daily food intake should be in the morning before the injection and the remaining feed should be given 6-8 hours later. In dogs treated twice daily, each part of the feed should be given before each injection with Caninsulin vet. Each meal should be fed at the same time each day.

Any adjustment of the insulin dose shall be done by a veterinarian by increasing and decreasing the daily dose by approximately 10% depending on symptoms and the results of measurements of blood glucose levels, however, no alterations more frequently than every three to four days.

Cat:
Caninsulin vet. must be injected subcutaneously and may not be administered intravenously.
The starting dose is 1 IU or 2 IU per injection based on the baseline blood glucose concentration, according to the following table.

Cat blood glucose concentration	Starting dose of Caninsulin vet. 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

Caninsulin vet. should be injected 2 times daily. The quality and quantity of the daily food intake should stay constant. The insulin dose depends on the degree of insulin insufficiency. This is

determined by a series of measurements of glucose in the blood, and varies from case to case.

Higher doses than 2 IU per injection is not recommended during the first three weeks of treatment.

Any adjustment of the insulin dose shall be done by a veterinarian by increasing and decreasing the daily dose. Increments by 1 unit per injection are recommended. Alterations should not be made more frequently than once a week.

Depending on the day-to-day variation in blood glucose levels and variations in insulin response over time, larger or more frequent increases in dose are not recommended.

Maintenance therapy:

Dogs and cast:
A long-term maintenance therapy should be determined when the insulin dose has been established and the animal is stabilized. Points in time should be set and agreed upon for detection of under-or overdose of insulin and insulin dose adjustments when necessary. Careful stabilization and monitoring will help to limit the chronic problems associated with diabetes, such as clouding of the eye lens in dogs and fatty liver in dogs and cats. The aim with the treatment is to reduce or eliminate the clinical signs of the disease by minimizing the occurrence of high blood glucose levels (hyperglycemia), especially in cats. The blood glucose concentrations shall be kept between 1 and 3 g/L (i.e. 100-300 mg/dl or 5.5 to 17 mmol/L) and a normal body weight should be kept.

9. Advice on correct administration

Caninsulin should be administered subcutaneously and must not be administered intravenously.
Shake the vial/cartridge 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 insulin is used. After this, the product should be gently mixed by turning the vial/cartridge back and forth a few times to maintain the homogeneous, uniformly milky suspension.
Agglomerates can form in insulin suspensions: do not use the product if the suspension does not have a homogeneous, uniformly milky appearance after shaking thoroughly.

Vial:
For the vial, specific syringes suitable for an insulin concentration of 40 IU/ml should be used.

Cartridge:
The cartridge should only be used with the insulin pen VetPen. VetPen is available in two versions: VetPen 8, which delivers 0.5 to 8 units per injection with every step, corresponding 0.5 units and VetPen 16, which delivers 1 to 16 units per injection with every step, corresponding 1 unit.
VetPen should only be used with 29 G/12 mm VetPen needles.
VetPen is accompanied by a separate instruction for use. The insulin pen must be used according to the manufacturer's instructions. The instructions for use must be followed carefully for how to load the cartridge, how to attach the needle and how to administer the insulin injection.
If the insulin pen is damaged or not working properly (due to mechanical defects) it has to be discarded and a new insulin pen has to be used.
If the insulin pen malfunctions (see the instructions for use of the pen), insulin suspension can be extracted from the cartridge with a syringe (suitable for an insulin concentration of 40 IU/ml) and injected.

Check and make notes on the animal's general condition; well-being, thirst and appetite.
Check the occurrence of glucose in the urine if deemed necessary by the veterinarian. The veterinarian checks the well-being of the animal and the pet owner's treatment journal every six months, or more frequently if there are any problems. Blood glucose samples should be taken at these times.

Insulin dose adjustment is made by a veterinarian. It must be based on a thorough analysis of the clinical data and laboratory results.

10. Withdrawal periods

Not applicable.

11. Special storage precautions

Keep out of the sight and reach of children.

Store in a refrigerator (2 °C – 8 °C).
Do not freeze.
Store in the original package. Protect from light.
Store in an upright position.

Vial: Shelf-life after first opening the immediate packaging when stored at 25 °C or below: 6 weeks .
Cartridge: Shelf-life after first opening the immediate packaging when stored at 25 °C or below: 4 weeks .
Do not use this veterinary medicinal product after the expiry date which is stated on the container.

12. Special precautions for disposal

Medicines should not be disposed of via wastewater or <household waste>.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

[*Marketing auhtorization numbers to be completed nationally.*]

Vials:
Carton box with 10 x 2.5 ml glass vials (Ph. Eur. Type I). Bromobutyl rubber stopper and sealed with an aluminium cap.
Carton box with 10 x 10 ml glass vials (Ph. Eur. Type I). Bromobutyl rubber stopper and sealed with an aluminium cap.

Cartridges:
Carton box with 10 x 2.7 ml glass cartridges (Ph. Eur. Type I) with a plunger, a rubber stopper and sealed with an aluminium cap.

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

2023-07-12

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

16. Contact details

Marketing authorisation holder <and contact details to report suspected adverse reactions>:
[to be completed nationally]

Manufacturer responsible for batch release:
Intervet International GmbH
Feldstrasse 1a
85716 Unterschleissheim
Germany

<Local representatives <and contact details to report suspected adverse reactions>:>
[to be completed nationally]

<For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.
<to be completed nationally>

17. Other information

Insulin with medium duration. Caninsulin vet. contains insulin porcine. After subcutaneous injection a marked effect on the blood glucose level is obtained after about 2 hours. The effect peaks at 7-12 hours post injection and the duration is approximately 24 hours in dogs.
In cats, the effect peaks at 1½ hours after the injection and the duration is about 10 hours.