

PARTICULARS TO APPEAR ON THE OUTER PACKAGE
Cardboard box (containing 1 x 10ml vial, 5 or 10 x 2.5 ml vials)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Caninsulin 40 IU/ml suspension for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:

Active substance:

Insulin porcine* 40 IU

*Containing 35 % amorphous zinc insulin and 65 % crystalline zinc insulin.

3. PACKAGE SIZE

10 ml

5 x 2.5 ml

10 x 2.5 ml

4. TARGET SPECIES

Dogs and cats.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

IMPORTANT: 40 IU/ml syringes must be used

Subcutaneous use.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}

Once broached use by...

Once broached use within 42 days.

9. SPECIAL STORAGE PRECAUTIONS

Before first use: Store upright in a refrigerator (2 °C – 8 °C).

After first opening: Store below 25 °C. Store the broached vial upright.

Do not freeze.

Keep the vial in the outer carton in order to protect from light.

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Intervet International B.V.

14. MARKETING AUTHORISATION NUMBERS

Vm 06376/4083

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE OUTER PACKAGE
Cardboard box (containing 10 x 2.7 ml cartridges)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Caninsulin 40 IU/ml suspension for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:

Active substance:

Insulin porcine * 40 IU

*Containing 35 % amorphous zinc insulin and 65 % crystalline zinc insulin.

3. PACKAGE SIZE

10 x 2.7 ml cartridges

4. TARGET SPECIES

Dogs and cats.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Subcutaneous use.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}

Once broached use by...

Once broached use within 42 days.

9. SPECIAL STORAGE PRECAUTIONS

Before first use: Store upright in the refrigerator (2 °C – 8 °C).

After first opening: Store below 25 °C.

Do not freeze.

Keep the cartridge in the outer carton in order to protect from light.

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Intervet International B.V.

14. MARKETING AUTHORISATION NUMBERS

Vm 06376/4083

15. BATCH NUMBER

Lot {number}

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING
UNITS VIAL LABEL (10 ml and 2.5 ml)**

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Caninsulin 40 IU/ml suspension for injection

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Each ml contains:
Insulin porcine 40 IU

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

Once broached use by....
Once broached use within 42 days.

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING
UNITS 2.7 ml CARTRIDGE LABEL**

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Caninsulin 40 IU/ml suspension for injection

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Each ml contains:
Insulin porcine 40 IU

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

Once broached use by...
Once broached use within 42 days.

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Caninsulin 40 IU/ml suspension for injection

2. Composition

Each ml contains:

Active substance:

Insulin porcine* 40 IU

*Containing 35% amorphous zinc insulin and 65 % crystalline zinc insulin.

Excipient:

Metacresol 3 mg

White to nearly white suspension for injection.

3. Target species

Dogs and cats.

4. Indications for use

The veterinary medicinal product is an intermediate acting insulin product containing porcine insulin, which is structurally identical to canine insulin. It is indicated in cases of diabetes mellitus (insulin deficiency) in dogs and cats, where the required blood levels are achieved by using an individually adjusted dose of the veterinary medicinal product.

5. Contraindications

Do not administer by the intravenous route.

The veterinary medicinal product is a medium duration insulin and is not intended for the treatment of animals with severe acute diabetes presenting in a ketoacidotic state.

Do not use in cases of hypoglycaemia.

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

6. Special warnings

Special warnings:

In the cat, diabetic remission is possible.

Special precautions for safe use in the target species:

Before the veterinary medicinal product is administered owners should be instructed to have a box of powdered glucose at home. Signs of hunger, increasing anxiety, unstable locomotion, muscle twitching, stumbling or sinking in the rear legs and disorientation indicate progression of hypoglycaemia and requires immediate administration of glucose solution and food to restore blood glucose levels.

Polyuria, polydipsia and polyphagia in combination in chronic cases with weight loss, general bad condition, loss of hair or abnormal furry coat and lethargy are the most common clinical symptoms of hyperglycaemia and require administration of insulin to restore blood glucose levels to the normal range.

The use of progestagens (oestrus inhibitors) in patients suffering from diabetes mellitus should be avoided.

Stress and irregular extra exercise must be avoided. Care must be taken with the use of corticosteroids. Ovariohysterectomy may have to be considered.

It is important to establish a strict feeding schedule in consultation with the owner which will include a minimum of fluctuations and changes.

Administration of the veterinary medicinal product must be carried out by an adult responsible for the welfare of the animal.

The veterinary medicinal product must be administered with specific U-40 sterile single-use syringes (vial) or with VetPen (cartridge).

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

Accidental self-injection can provoke clinical signs of hypoglycaemia and there is a low possibility of an allergic reaction. Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

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

In the unlikely event of accidental eye and skin contact, wash the area with clean, running water.

Pregnancy and lactation:

The use of the veterinary medicinal product is not contraindicated 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 interaction:

Changes in insulin requirements may result from administration of substances which alter glucose tolerance, such as corticosteroids, thiazide diuretics, progestogens, amitraz and alpha-2 agonists, such as medetomidine, dexmedetomidine, xylazine. Monitoring of glucose concentrations should be used to adjust the dose accordingly. Similarly, changes in diet or exercise may alter insulin requirements.

Overdose:

Insulin overdose can result in clinical symptoms of hypoglycemia. Before the product is administered owners should be instructed to have a box of powdered glucose at home. Signs of hunger, increasing anxiety, unstable locomotion, muscle twitching, stumbling or sinking in the rear legs and disorientation indicate progression of hypoglycaemia and require immediate administration of glucose solution and food to restore blood glucose levels.

Hypoglycemia, as a result of an overdose of insulin, may trigger a hormonal response and a release of glucose (Somogyi overswing). (See section 8).

Major incompatibilities:

None known.

7. Adverse events

Dogs and cats:

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

*The reaction is usually mild and reversible. Local injection site reactions are reported very rarely in cats.

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:

Website: <https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine>

e-mail: adverse.events@vmd.gov.uk

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

Subcutaneous use.

The veterinary medicinal should be administered once or twice daily, as appropriate, by subcutaneous injection. Alternate the injection site daily. Before first use, shake the vial thoroughly until a homogeneous, uniform milky suspension is obtained. Foam on the surface of the suspension formed during shaking should be allowed to disperse before the veterinary medicinal product is used and, before each subsequent use, the veterinary medicinal product should be gently mixed to maintain a homogeneous, uniformly milky suspension before use. Agglomerates can form in insulin suspensions: do not use the veterinary medicinal product if visible agglomerates persist after shaking thoroughly.

Vials: Before each use, invert the vial a few times before use until a homogenous suspension is obtained. A 40 IU/ml insulin syringe should be used.

Cartridge: Before each use, invert the vial a few times before use until a homogenous suspension is obtained. The glass cartridge is designed to be used with the injector VetPen 8 or VetPen 16. VetPen is accompanied by a package leaflet with detailed instructions for use to be followed.

The injection procedure when using VetPen is as follows:

1. Peel the protective film from a new pen needle. Screw the pen needle straight onto the cartridge holder. Remove the outer protective needle cap from the pen needle.
Replace the pen cap onto the insulin pen. Turn the pen up and down at least 10 times.
2. **It is important to remove the air from the cartridge (prime the pen) before use to avoid injection of air and ensure proper dosing. Dial 1 unit on the dose selector. Remove the pen cap and the needle cap.**
Position the pen carefully with the needle pointing vertically upwards. Tap the cartridge gently with your finger a few times to push any air bubbles to the top of the cartridge. Push and hold the release button towards the needle until the arrow (▶) on the pen body points to the start line (—) on the dose selector. A small amount of insulin may appear at the needle tip before the pen is fully primed. Repeat steps 1 and 2 until insulin drips actively or squirts out of the needle tip. Confirm that the pen is fully primed by ensuring that the air bubble is no longer visible in the cartridge window during inversion. The insulin pen is now primed and ready for use.
3. Make sure the arrow (▶) on the pen body points to the start line (—) on the dose selector. If it does not, please refer to 'Priming Advice' on the leaflet supplied with the VetPen.
4. Dial up the number of units required per your veterinary surgeon's direction. **Never attempt to forcefully dial back the dose selector, as doing so may damage the insulin pen and result in inaccurate dosing. If at any time you select too high a dose, we recommend that the incorrect dose is fully expelled into a safe place and the required dose is redialed. Make sure before injecting that the arrow (▶) points towards the correct number of units on the dose selector.**
5. The injection should be performed subcutaneously, 2 to 5 cm (¾ to 2 in) from the dorsal midline, varying from behind the scapulae (shoulder) to the mid-lumbar region (mid-back) and alternating sides. Insert the needle using the injection technique recommended by your veterinary surgeon then push the release button towards the pen needle and hold it in place until the start line on the dose selector returns to the arrow on the pen body (▶—).
Releasing the button prematurely will result in incomplete delivery of the dose. After the start line returns to the arrow, wait for a **minimum of 5 seconds** before removing the needle from the skin.

If the needle is removed or dislodged from the skin too early, you may observe small drops of insulin leaking from the needle, which can result in incomplete dosing. If this occurs, do not attempt to re-dose. Wait and give your pet its usual dose at the next

injection.

If the dose selector stops before the start line on the dose selector (—) returns to the arrow on the pen body (▶), this indicates that your pet has not received a full dose. If only a partial dose is administered, do not attempt to re-dose. Wait and give your pet its usual dose at the next injection.

A once daily injection is sufficient to reduce the blood glucose concentration in most diabetic dogs. However, the duration of action may vary, making it necessary to administer the insulin dose twice daily to some diabetic dogs.

In diabetic cats, it is necessary to administer the veterinary medicinal product twice daily.

The dose depends on the degree of deficit in the animal's own insulin production and is therefore different in each case.

Stabilisation phase

Dog: Insulin therapy is initiated with the starting dose of **0.5 to 1.0 IU/kg** bodyweight once daily, rounded down to the lowest entire number of units.

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 days.

The duration of insulin action as determined by blood glucose curve, 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 new doses should be administered at 12-hour intervals. Further dose adjustments should be made progressively as previously explained. Following switching to twice daily dosing, it is recommended that the clinical signs and blood glucose response be monitored closely.

To achieve a balance between the generation of glucose and the effect of the veterinary medicinal product, feeding should 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 second meal is usually fed at the time of peak insulin effect. In dogs treated twice daily, feeding coincides with insulin administration. Each meal should be fed at the same time each day.

Cat: The initial dose is **1 IU or 2 IU** 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 starting dose should not exceed 2 IU per injection.

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. 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 program 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 concentration). Adjustments to the insulin dose should be made based on interpretation of the clinical signs supported by the laboratory results.

Somogyi overswing, also called rebound hyperglycaemia, is a response to an overdose of insulin insufficient to cause, potentially fatal, hypoglycaemia. As 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 glycosuria for part of the 24-hour cycle. There is a danger that the Somogyi overswing 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.

The ability of pet owners to recognise the signs of hypo- or hyperglycaemia and respond appropriately is very important.

9. Advice on correct administration

Vial: a 40 IU/ml insulin syringe should be used.

Cartridge: injection should be performed using VetPen 8 or VetPen 16. Please read the instructions included with the VetPen carefully prior to use.

When changing between dosing devices (syringes or VetPen), owners should be advised to monitor their animal closely to detect any changes in behaviour or clinical condition.

A dose adjustment may be required.

10. Withdrawal periods

Not applicable.

11. Special storage precautions

Keep out of the sight and reach of children.

Before first use: Store upright in a refrigerator (2 °C – 8 °C).

After first opening: Store below 25 °C. Store the broached vial upright.

Do not freeze.

Keep the vial/cartridge in the outer carton in order to protect from light.

Do not use this veterinary medicinal product after the expiry date which is stated on the label and carton after Exp. The expiry date refers to the last day of that month.

Shelf life after first opening the immediate packaging: 42 days.

12. Special precautions for disposal

Medicines should not be disposed of via wastewater.

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 NUMBER AND PACK SIZES

Vm 06376/4083

Pack sizes:

Cardboard box with 5 or 10 glass vials of 2.5 ml.

Cardboard box with 1 glass vial of 10 ml.

Cardboard box with 10 glass cartridges of 2.7 ml.

Not all pack sizes may be marketed.

15. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

16. Contact details

Marketing authorisation holder:

Intervet International B.V.
Wim de Körverstraat 35
5831 AN Boxmeer
Netherlands

Manufacturer responsible for batch release:

Intervet International GmbH
Feldstrasse 1a
85716 Unterschleissheim
Germany

Local representative:

MSD Animal Health UK Limited
Walton Manor, Walton
Milton Keynes
MK7 7AJ, United Kingdom

Contact details to report suspected adverse reactions:

UK(GB)

MSD Animal Health UK Ltd.
Tel.: +44 (0)1908 685685

UK(NI)

Intervet Ireland Ltd.
Tel.: +353 (0)1 2970220

Distributor in Northern Ireland:

Intervet Ireland Ltd.
Magna Drive, Magna Business Park
Citywest Road, Dublin 24
Ireland

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

17. Other information

POM-V

Gavin Hall

Approved: 11 February 2026