

PARTICULARS TO APPEAR ON THE OUTER PACKAGE {Carton for 20mL}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ProZinc 40 IU/ml suspension for injection for dogs

2. STATEMENT OF ACTIVE SUBSTANCES

40 IU/ml of insulin human

3. PACKAGE SIZE

20 ml

4. TARGET SPECIES

Dogs.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Subcutaneous use.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}
Once broached use within 60 days.

9. SPECIAL STORAGE PRECAUTIONS

Store upright in a refrigerator.
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

Boehringer Ingelheim Vetmedica GmbH

14. MARKETING AUTHORISATION NUMBER

Vm 04491/5065

15. BATCH NUMBER

Lot {number}

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING
UNITS {Vial, 20mL}**

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ProZinc

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

40 IU/ml

20 ml

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

Once broached use within 60 days.

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

ProZinc 40 IU/ml suspension for injection for dogs

2. Composition

Each ml contains:

Active substance:

Insulin human*40 IU as
protamine zinc insulin.

One IU (International Unit) as protamine zinc insulin equivalent to 0.0347 mg of insulin human.

*produced by recombinant DNA technology.

Excipients :

Protamine sulfate	0.466 mg
Zinc oxide	0.088 mg
Phenol	2.5 mg

Cloudy, white, aqueous suspension.

3. Target species

Dogs

4. Indications for use

For the treatment of diabetes mellitus in dogs to achieve reduction of hyperglycaemia and improvement of associated clinical signs.

5. Contraindications

Do not use for the acute management of diabetic ketoacidosis.

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

6. Special warnings

Special warnings:

Very stressful events, inappetence, concomitant treatment with gestagens and corticosteroids or other concomitant diseases (e.g. gastro-intestinal, infectious or inflammatory or endocrine diseases), might influence insulin effectiveness and therefore the insulin dose may need to be adjusted.

Special precautions for safe use in the target species:

The insulin dose may need to be adjusted or discontinued after resolution of transient diabetic stages (e.g. dioestrus-induced diabetes mellitus, diabetes mellitus secondary to hyperadrenocorticism).

After the daily insulin dose is established, monitoring for diabetic control is recommended.

Treatment with insulin can cause hypoglycaemia, for clinical signs and appropriate treatment, please refer to section "Overdose", below.

In cases where hypoglycaemia is suspected, blood glucose measurements should be taken at the time of occurrence (if possible) as well as shortly prior to the next feeding/injection (where applicable).

Stress and irregular exercise should be avoided. It is recommended to establish a regular twice daily feeding schedule with the owner whether injecting insulin once or twice daily.

In an experimental study in healthy dogs, median time to blood glucose nadir was approximately 16 and 12 hours following administration of 0.5 or 0.8 IU/kg bodyweight, respectively.

Under clinical field conditions in diabetic dogs, time to maximal effect in lowering blood glucose concentrations (i.e. blood glucose nadir) after subcutaneous administration was not observed within 9 hours after last injection in 67.9% of dogs overall. (73.5% on once daily and 59.3% on twice daily administration).

Consequently, blood glucose curves should be conducted over a sufficient period to determine a blood glucose nadir.

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 may be treated by oral administration of sugar. There is a low possibility of an allergic reaction in sensitised individuals.

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

Pregnancy and lactation:

The safety of the veterinary medicinal product has not been established during breeding, pregnancy and lactation.

Use only according to the benefit-risk assessment by the responsible veterinarian. In general, insulin requirements during pregnancy and lactation might be different due to a change in the metabolic state. Therefore, close glucose monitoring and veterinary supervision is advised.

Interaction with other medicinal products and other forms of interaction:

Changes in insulin requirements may result from administration of substances which alter glucose tolerance (e.g. corticosteroids and gestagens). Monitoring of glucose concentrations should be performed to adjust the dose accordingly. Similarly,

changing the diet may alter insulin requirements and necessitate a change of insulin dose.

Overdose:

An overdose of insulin can result in hypoglycaemia in which case immediate administration of a glucose containing solution or gel and/or food is required.

Clinical signs may include hunger, increasing anxiety, unstable locomotion, muscle twitching, stumbling or sinking in the rear legs and disorientation.

Insulin administration should be temporarily stopped and the next dose of insulin adjusted appropriately.

The owner is advised to have glucose containing products (e.g. honey, dextrose gel) in the household.

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:

Very common (> 1 animal in 10 animals treated):

Hypoglycaemia (increased appetite, anxiety, twitching, stumbling gait¹, disorientation)².

Very rare (< 1 animal in 10,000 animals treated, including isolated reports):

Injection site reactions³.

- 1 Unstable locomotion and sinking in the rear legs.
- 2 Generally mild in nature. Immediate administration of a glucose containing solution or gel and/or food is required. Insulin administration should be temporarily stopped and the next dose of insulin adjusted appropriately.
- 3 Resolved without cessation of therapy.

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 its local representative using the contact details at the end of this leaflet, or via your national reporting system.

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

Subcutaneous use.

If the animal owner is to administer the veterinary medicinal product, suitable training/advice should be provided by the prescribing veterinarian before using for the first time.

Dosage:

The veterinarian should re-evaluate the animal at appropriate intervals and make adjustments to the treatment protocol, for instance dose and dosing regimen, until adequate glycaemic control has been attained.

Any dose adjustment (i.e. increase of dose) should be in general performed after several days (e.g. 1 week) since full action of insulin requires an equilibration phase. Dose reductions due to observed hypoglycaemia or suspected Somogyi effect (rebound hyperglycaemia) may be of 50% or higher (potentially including a temporary pause of insulin administration).

Once adequate glycaemic control is achieved intermittent glucose monitoring should be performed, especially when there is a change in clinical signs, and further adjustments in the insulin dose might be necessary.

General guidance:

Dosing should be individualised and based on the clinical presentation of each patient. To achieve optimal control of diabetes mellitus, dose adjustments should primarily be based on clinical signs. Blood parameters such as fructosamine, maximum blood glucose and decrease of blood glucose concentrations in blood glucose curves conducted over a sufficient period of time to determine a blood glucose nadir should be used as supporting tools (see also section “Special precautions for use in animals”).

Re-evaluation of clinical signs and laboratory parameters should be performed as recommended by the attending veterinarian.

Initiation:

For initiation of treatment, the recommended dose is 0.5 to 1 IU insulin/kg bodyweight once daily every morning (approx. every 24 hours).

For newly diagnosed diabetic dogs, a starting dose of 0.5 IU insulin/kg once daily is recommended.

Management:

Adjustments of insulin dose on a once daily regimen, if required, should generally be done in a conservative and gradual manner, (e.g. up to 25% increase/decrease of the dose per injection).

If insufficient improvement in diabetic control is observed after an adequate dose adjustment period of 4 to 6 weeks on once daily treatment, the following options may be considered:

- Further adjustments of insulin dose on once daily treatment may be necessary; in particular if dogs undertake increased physical activity, have a change of their usual diet or during concomitant illness.
- Switching to twice daily dosing: In such cases, it is recommended to reduce the dose per injection by one third (e.g. 12 kg dog being treated once daily with 12 IU insulin/injection may be switched to 8 IU insulin/injection administered twice daily). The veterinary medicinal product should be administered in the morning and in the evening, approx. 12 hours apart. Further adjustments of insulin dose on twice daily treatment may be necessary.

Depending on the underlying cause (e.g. dioestrus-induced diabetes mellitus), dogs can develop diabetic remission, although seldom. In those cases sufficient endogenous insulin production will be regained and the exogenous insulin dose will need to be adjusted or ceased.

9. Advice on correct administration

A U-40 syringe must be used.

The suspension should be mixed by gently rolling the vial prior to withdrawing each dose from the vial.

Particular care should be taken with regard to the accuracy of dosing.

The veterinary medicinal product should be administered by subcutaneous injection.

The dose should be given concurrently with or immediately after a meal.

Avoid introduction of contamination during use.

After gently rolling the vial, veterinary medicinal product suspension has a white, cloudy appearance.

A white ring may be seen in the neck of some vials, but this does not affect the quality of the veterinary medicinal product.

Agglomerates (e.g. clumps) can form in insulin suspensions: do not use the veterinary medicinal product if visible agglomerates persist after gently rolling the vial.

10. Withdrawal periods

Not applicable.

11. Special storage precautions

Keep out of the sight and reach of children.

Store upright in a refrigerator (2 °C – 8 °C).

Do not freeze.

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

Shelf life after first opening the container: 60 days.

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

12. Special precautions for disposal

Medicines should not be disposed 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

Vm 04491/5065

Package size: Cardboard box with one 20 ml vial.

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 and manufacturer responsible for batch release:

Boehringer Ingelheim Vetmedica GmbH
Binger Strasse 173
55216 Ingelheim am Rhein
Germany

Local representatives and contact details to report suspected adverse reactions:

United Kingdom (Great Britain)

Boehringer Ingelheim Animal Health UK Limited
Bracknell, RG12 8YS, UK
Tel: +44 1344 746957

17. Other information

POM-V

Gavin Hall
Approved: 18 August 2025