ProZinc®
(protemic zinc recombinant human insulin)

Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Description: ProZinc insulin is a sterile aqueous protemic zinc suspension of recombinant human insulin.

Each mL contains:
recombinant human insulin 40 International Units (IU)
protemic sulfate 0.446 mg
zinc oxide 0.080 mg
glucoron 16.0 mg
diisae sodium phosphate, hexahydrate 3.78 mg
phenol (added as preservative) 2.50 mg
hydrochloric acid 1.63 mg
water for injection (maximum) 1005 mg
pH is adjusted with hydrochloric acid and/or sodium hydroxide.

Indication: ProZinc (protemic zinc recombinant human insulin) is indicated for the reduction of hyperglycemia and hypoglycemia-associated clinical signs in cats with diabetes mellitus.

Dosage and Administration: USE OF A SYRINGE OTHER THAN A U-40 SYRINGE WILL RESULT IN INCORRECT DOSING.

For SCUBUTANEOUS INJECTION IN CATS ONLY.

ProZinc insulin should be mixed by gently rolling the vial prior to withdrawing each dose from the vial. Using a U-40 insulin syringe, the injection should be administered subcutaneously on the back of the neck or on the side of the cat.

Always provide the Cat Owner Information Sheet with each prescription. The initial recommended ProZinc dose is 0.1 – 0.3 IU insulin/pound of body weight (0.2 – 0.7 IU/kg) every 12 hours. The dose should be given concurrently with or right after a meal. The veterinarian should re-evaluate the cat at appropriate intervals and adjust the dose based on both clinical signs and glucose nadirs until adequate glycemic control has been attained. In the effectiveness field study, glycemic control was considered adequate if the glucose nadir from a 9-hour blood glucose curve was between 80 and 150 mg/dL and clinical signs of hyperglycemia such as polyuria, polydipsia, and weight loss were improved.

Further adjustments in the dosage may be necessary with changes in the cat’s diet, body weight, or concomitant medication, or if the cat develops concurrent infection, inflammation, neoplasia, or an additional endocrine or other medical disorder.

Contraindications: ProZinc insulin is contraindicated in cats sensitive to protemic zinc recombinant human insulin or any other ingredients in the ProZinc product. ProZinc insulin is contraindicated during episodes of hypoglycemia.

Cat Owner Information about ProZinc®
(protemic zinc recombinant human insulin)

ProZinc insulin is indicated for the reduction of hyperglycemia and hypoglycemia-associated clinical signs in cats with diabetes mellitus. This summary contains important information about ProZinc insulin. You should read this information before you start giving your cat ProZinc insulin and review it each time the prescription is refilled. This sheet is provided only as a summary and does not take the place of instructions from your veterinarian. Talk to your veterinarian if you do not understand any of this information or if you want to know more about ProZinc insulin.

ProZinc insulin is an aqueous protemic zinc suspension of recombinant human insulin that is used to reduce hyperglycemia (high blood glucose or high blood sugar) in cats with diabetes mellitus. A licensed veterinarian must prescribe ProZinc insulin for your cat. ProZinc insulin should be given to cats only. Keep out of reach of children. Use medical attention immediately if you accidentally inject yourself with ProZinc insulin.

What is diabetes mellitus?
Diabetes mellitus occurs when a cat has insufficient levels of, or an abnormal response to, insulin. The low insulin levels may result in high blood glucose that could produce the following changes in your cat:
• Increased thirst
• Increased urination
• Increased appetite
• Weight loss
• High levels of glucose in the urine (glycosuria)
• Weakness in the back legs

What kind of results can I expect when my cat is on ProZinc insulin for diabetes mellitus?
Although ProZinc insulin is not a cure for diabetes mellitus, it can help reduce the levels of glucose in the blood, which can help alleviate the clinical signs.

What should I discuss with my veterinarian before giving ProZinc insulin?
Talk to your veterinarian about:
• The signs of diabetes mellitus you have observed (for example, increased thirst and urination).
• The importance of proper insulin storage and administration techniques (for example, how to gently roll the vial prior to each use, how to fill the U-40 syringe with the proper amount of insulin, and where and how to inject the insulin).
• The importance of maintaining the cat under the same conditions for diet, exercise, environment, etc.
• The importance of follow-up visits for testing to determine if dose adjustments of ProZinc insulin are necessary.

Tell your veterinarian about:
• Any side effects your cat has had when receiving other insulin products.
• Any medical problems or allergies that your cat has now or has had in the past.
• All medications that you are giving your cat or plan to give your cat, including those you can get without a prescription.
• If your cat is pregnant, nursing, or if you plan to breed your cat.

What are the possible side effects that may occur in my cat during ProZinc therapy?
ProZinc insulin, like other drugs, may cause some side effects. Serious side effects can occur with or without warning. Please contact your veterinarian immediately if you think your cat has a medical problem or side effect from ProZinc therapy. The most common insulin-related side effect is low blood glucose (hypoglycemia). Signs of hypoglycemia may occur suddenly and can include:
• Weakness
• Depression, lethargy, sluggishness
• Staggering gait
• Behavioral changes

ProZinc therapy can cause the following side effects:
• Muscle twitching
• Seizures
• Coma
• Death

Warnings: User Safety: For use in cats only. Keep out of the reach of children. Avoid contact with eyes. In case of contact, immediately flush eyes with running water for at least 15 minutes. Accidental injection may cause hypoglycemia. In case of accidental injection, seek medical attention immediately. Exposure to product may induce a local or systemic allergic reaction in sensitized individuals.

Animal Safety: Owners should be advised to observe for signs of hypoglycemia (see Cat Owner Information Sheet). Use of this product, even at established doses, has been associated with hypoglycemia. An animal with signs of hypoglycemia should be treated immediately. Glucose should be given orally or intravenously as dictated by clinical signs. Insulin should be temporarily withheld and, if indicated, the dosage adjusted. Any change in insulin should be made cautiously and only under a veterinarian’s supervision. Changes in insulin strength, manufacturer, type, species (human, animal) or method of manufacture (rDNA versus animal-source insulin) may result in the need for a change in dosage. Appropriate diagnostic tests should be performed to rule out other endocrinopathies in diabetic cats that are difficult to regulate.

Pullets: Animals presenting with severe ketosis, anorexia, lethargy, and/or vomiting should be stabilized with short-acting insulin and appropriate supportive therapy until their condition is stabilized. As with all insulin products, careful patient monitoring for hypoglycemia and hyperglycemia are essential to attain and maintain adequate glycem control and to prevent associated complications. Overdosage can result in profound hypoglycemia and death. Progestogens, certain endocrinopathies and glucocorticoids can have an antagonistic effect on insulin activity. Progestogen and glucocorticoid use should be avoided.

Adverse Reactions: Effectiveness Field Study
In a 45-day effectiveness field study, 176 cats received ProZinc insulin. Hypoglycemia (defined as a blood glucose value of 50 mg/dL) occurred in 71 of the cats at various times throughout the study. Clinical signs of hypoglycemia were generally mild in nature (described as lethargic, sluggish, weak, trembling, uncoordinated, groggy, glazed-eyed or dazed). In 17 cases, the veterinarian provided oral glucose supplementation or food as treatment. Most cases were not associated with clinical signs and received no treatment. One cat had a serious hypoglycemic event associated with stupor, lateral recumbency, hypothermia and seizures.
How should I give ProZinc insulin to my cat?

• Is not eating or is vomiting.

Do not give your cat its prescribed dose of ProZinc insulin if it:

When should my cat not be given ProZinc insulin?

• When eating.

What actions do I take if my cat shows signs of hypoglycemia?

What should I do if I inject more than the prescribed amount of ProZinc insulin?

Contact your veterinarian immediately and, if your veterinarian is not available, seek other veterinary advice at once.

What else should I know about ProZinc insulin?

This sheet provides a summary of information about ProZinc insulin. If you have any questions or concerns about the product or diabetes mellitus, talk to your veterinarian.

As with all prescribed medications, ProZinc insulin should only be given to the cat for which it is prescribed and for the condition for which it was prescribed. It is important to periodically discuss your cat's response to ProZinc insulin with your veterinarian.

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ProZinc insulin should be stored in an upright position under refrigeration at 36-46°F (2-8°C). Do not freeze. Protect from light.

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