

<b><u>CANINSULIN – CANADA FAQ</u></b>
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**1. What is CANINSULIN?**

CANINSULIN is a prescription drug that contains porcine insulin zinc suspension in both amorphous and crystalline forms. It is indicated for the management of hyperglycemia and its associated clinical signs in dogs and cats with diabetes mellitus.

**2. Why has Health Canada and Intervet/Schering-Plough Animal Health issued a CANINSULIN alert?**

The product has been found to be out of specification in regards to the long term stability of the crystalline, or long acting, component. Specifically, the concentration of the crystalline component may be higher than what is outlined in the specifications of the product. Consequently, the amorphous, or short-acting, component may have a lower concentration. This could mean that diabetic patients on CANINSULIN may experience a delay in onset of action, a delay in peak activity and an overall extension of the duration of activity, although at this time this occurrence has not been documented.

**3. Is CANINSULIN being recalled?**

No. The product is remaining in distribution and supplies will not be limited. Veterinarians can continue to prescribe the product for their diabetic patients and can also continue to start treating any newly diagnosed diabetic patients with CANINSULIN.

**4. Is Intervet/Schering-Plough Animal Health Canada and Health Canada asking veterinarians to transition diabetic pets from CANINSULIN?**

Intervet/Schering-Plough Animal Health and Health Canada are not asking veterinarians to transition diabetic pets from CANINSULIN. Any newly diagnosed patients can also be started on CANINSULIN and current diabetic patients can be maintained on CANINSULIN.

**5. What is Intervet/Schering-Plough Animal Health doing to rectify the issue?**

Our company is working diligently with the Health Canada Veterinary Drugs Directorate to address the issue.

**6. Are there specific serials that are in question, or are all serials affected?**

The alert pertains to all unexpired serials of CANINSULIN currently in the field.

**7. Should I be concerned about the safety or efficacy of the CANINSULIN that animals are receiving?**

Based on the results of in vivo pharmacodynamic and pharmacokinetic studies evaluating glucose and insulin levels, respectively, and because Intervet/Schering-Plough Animal Health has not documented an increase in either adverse event rates or efficacy issues with the product, it is our initial assessment that this finding should not adversely affect either the efficacy or the safety of CANINSULIN. We urge you, however, to continue to monitor animals closely for a delay in the onset of action, a delay in peak activity and an overall extension of the duration of activity or any signs of hyper or hypoglycemia.

We request that you report any potential concerns with efficacy or safety, and direct any questions, to our technical services department at 1-866-683-7838.

**8. What are the signs of hypoglycemia (low blood sugar)?**

Clinical signs of hypoglycemia include depression, lethargy, disorientation, ataxia (lack of coordination), and seizures.

**9. What are the signs of hyperglycemia (high blood sugar)?**

Clinical signs of hyperglycemia include polyuria (excessive urination), polydipsia (excessive thirst), polyphagia (overeating), and weight loss.

**10. Has there been an increase recently in reports of efficacy or safety concerns with CANINSULIN?**

Intervet/Schering-Plough Animal Health has not documented an increase in either adverse event rates or efficacy issues with the product.

**11. Are either species (dogs or cats) more affected by this finding?**

No. No increase in adverse events or efficacy issues has been reported in either species, but we would not expect any differences between dogs and cats.