



Intervet Canada Corp.
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November 12th, 2009

Re: CANINSULIN® Product Alert

Dear Doctor,

Intervet/Schering Plough Animal Health, as a responsible manufacturer of quality veterinary products, would like to inform you that we have determined that serials of CANINSULIN® porcine insulin zinc suspension have stability test results that are above specification on an indicator of the amount of crystalline insulin in the formulation. We want to advise you that we are working diligently with Health Canada Veterinary Drugs Directorate and our Quality Control and Research Departments to determine the significance of this finding and permanently address this issue.

CANINSULIN contains two insulin components: crystalline insulin, the longer-acting component, and amorphous insulin, the short-acting component. This finding regarding the crystalline component could potentially result in your patients experiencing a delay in the 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.

We take all out-of-specification results very seriously and deemed it appropriate to notify you of this situation. Accordingly, we request that you continue to closely monitor your patients receiving CANINSULIN for any changes in onset or duration of activity, or for any signs of hyperglycemia or hypoglycemia. The classic signs of hyperglycemia would include polyuria, polydipsia, polyphagia, weight loss and lethargy. The classic signs of hypoglycemia would include disorientation, ataxia, weakness, lethargy and seizures. Intervet/Schering-Plough Animal Health has recently conducted *in vivo* pharmacodynamic and pharmacokinetic studies evaluating glucose and insulin levels with out-of-specification product. In addition, Intervet/Schering-Plough Animal Health has not documented any increase in either the safety or efficacy adverse event rates. Based on the *in vivo* studies and the review of adverse event rates, it is our initial assessment that the stability test findings described above should not adversely affect either the efficacy or the safety of CANINSULIN, but we urge you to continue to closely monitor your patients in any event. We request that you report any of the above clinical signs or concerns with efficacy or safety, and direct any questions, to our Technical Services Department at 1-866-683-7838. If any of your clients have any questions, please direct them to 1-866-683-7838.

Thank you for your ongoing confidence in our company to provide you quality products and service.

Sincerely,

Dr. Hélène Langlois, DMV, MBA
Director, Regulatory Affairs