

November 6, 2009

Re: Vetsulin® 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 Vetsulin® 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 the FDA Center for Veterinary Medicine and our Quality Control and Research Departments to determine the significance of this finding and permanently address this issue.

Vetsulin 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 Vetsulin 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. Based on *in vivo* pharmacodynamic and pharmacokinetic studies respectively evaluating glucose and insulin levels 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 Vetsulin, 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 1-800-224-5318. Information regarding this issue can also be found on Intervet/Schering-Plough Animal Health's website at [www.vetsulin.com](http://www.vetsulin.com). If any of your clients have any questions, please direct them to the website or to 1-800-224-5318.

During this period of time while we work on this issue, supplies of Vetsulin may be limited and therefore you should consider starting all new diabetic patients on non-Vetsulin insulin products and transitioning existing diabetic patients to other insulins. If you have Vetsulin inventory concerns as a result of the transition to alternative insulins, please contact Intervet/Schering-Plough Animal Health Customer Service at 1-800-521-5767 or your distributor.

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

Sincerely,

A handwritten signature in black ink that reads "Christopher Pappas Jr. DVM". The signature is written in a cursive, flowing style.

Christopher Pappas Jr., DVM, Director of Technical Services

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