

FINAL VETSULIN ALERT FAQ's

Last Updated January 8, 2010, 1:30 PM EDT

CONTACT INFORMATION

For Customer Service issues, call 1-800-521-5767

For Technical Service issues, call 1-800-224-5318

For Media Relations, call Sharon Dilling, 1 862 -245 -3390.

General Questions

1. What is VETSULIN®?

VETSULIN 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 FDA and Intervet/Schering-Plough Animal Health issued a VETSULIN 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 is 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 VETSULIN may experience a delay in onset of action, a delay in peak activity and an overall extension of the duration of activity.

3. Is VETSULIN being recalled?

No. The product is remaining in distribution, but supplies will soon be exhausted. Veterinarians should plan on transitioning their diabetic patients to other insulin products and should not be starting any newly diagnosed diabetic patients on Vetsulin.

4. Why is Intervet/Schering-Plough Animal Health asking veterinarians to transition diabetic pets from VETSULIN to other insulin products?

In its alert, FDA recommended that veterinarians consider transitioning their patients to other insulins. Due to the fact that we do not know when the situation will be resolved, supply shortages are expected, and the supply of VETSULIN will soon be exhausted. Our primary goal is protecting the health of patients. Therefore, Intervet/Schering-Plough Animal Health is asking veterinarians not to start any newly diagnosed patients on VETSULIN and to begin transitioning current diabetic patients off VETSULIN and on to other insulin products.

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

Our company, including our Quality Assurance and Research and Development departments, is working diligently with the FDA to address the issue.

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

The FDA Alert pertains to all unexpired serials of Vetsulin currently in the field.

7. Should I be concerned about the safety or efficacy of the VETSULIN that my patients are receiving?

Based on the results of limited *in vivo* pharmacodynamic and pharmacokinetic studies evaluating glucose and insulin levels, respectively, and on a review of pharmacovigilance data, it is our initial assessment that this finding should not adversely affect either the efficacy or the safety of Vetsulin.

This pharmacovigilance review compared affected serials of VETSULIN versus historical serials of VETSULIN and did not demonstrate a significant difference in adverse events or efficacy issues.

We urge you, however, to continue to monitor your patients 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 1-800-224-5318.

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

No, we would not expect any differences between dogs and cats.

11. Will VETSULIN be available again in full supply? If so, when?

Intervet/Schering-Plough Animal Health is working diligently with the FDA to rectify the situation. At this time we cannot speculate on how long VETSULIN will be unavailable or in limited supply.

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