

PreveNile® West Nile Virus Vaccine Recall Frequently Asked Questions

Date: 5-14-2010

Customer Services (product returns): 1-800-521-5767

Technical Services (adverse event reporting): 1-866-349-3497

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Q. What is PreveNile?

A. PreveNile is for the vaccination of healthy horses to prevent viremia and as an aid in the prevention of disease and encephalitis caused by West Nile virus infection.

Q. Why has Intervet initiated a voluntary recall of PreveNile?

A. Intervet Inc. initiated a voluntary recall of PreveNile following increased reports of adverse events (AEs) in horses following vaccination. The recall includes all PreveNile serials. Intervet is no longer making PreveNile available while it investigates the cause of the adverse events.

Q. Are there specific serials that are in question?

A. The recall includes all PreveNile serials. Intervet is no longer making PreveNile available while it investigates the cause of the adverse events.

Q. I have a vial of PreveNile and I do not see the serial number that is on the vial on the list of recalled serials mentioned in your letter. Does this mean I can keep the product and that it is safe to use?

A. The control number mentioned in the letter corresponds to the number on the outside packaging (PreveNile box). There are separate serial numbers on the vials themselves. The vaccine has one serial number, the diluent has another. The numbers listed in the letter are those on the packaging itself. **However, all PreveNile – regardless of serial or control number – is being recalled.**

If you are a vet contact your distributor or point of purchase for details on return and credit. If you are a Horse Owner, please contact the veterinarian from whom you purchased the product.

Q. Should veterinarians be concerned about the safety or efficacy of PreveNile?

A. The voluntary recall of PreveNile was initiated by Intervet following increased reports of adverse events in horses following vaccination. These reports were inconsistent with data reported in our clinical studies with PreveNile.

As mentioned in the product label, in a large field study of 919 horses, PreveNile was demonstrated to be >99% reaction-free when administered to horses of various ages, breeds, and sex. (Source: product label)

Q. What is Intervet doing to implement the recall?

A. Intervet has contacted all veterinarians and posted the recall on www.prevenile.com. Our sales force is speaking with veterinarians to ensure they are aware of the recall. To return the product, veterinarians should contact their distributor or point of purchase for details on return and credit. Horse Owners should contact the veterinarian from whom the product was purchased.

Q. What is a Voluntary Recall? Does this mean I can decide not to return the vaccine and continue using it?

A. A Voluntary Recall means that *our company has voluntarily chosen* to recall this product. This was not a United States Department of Agriculture, Center for Veterinary Biologics mandated recall. We also voluntarily notified USDA, CVB of our intent to recall the product. You should discontinue using the product and return it as soon as possible.

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