



Knowledge

Immunoglobulins: the right choice in the right circumstances

SUMMARY:

Sera from immunized hosts have been used successfully to treat various infectious diseases for over 100 years. The first antibody-based treatment, a diphtheria antiserum, was developed in 1901.

Today, scientific advancements in the production of antibody-based products – coupled with the growing need for new treatment options – are causing a resurgence in immunoglobulin therapies. And innovative technologies and rigorous testing procedures are assuring new levels of product safety, quality and efficacy.

Immunoglobulin treatments offer versatility, specificity and immediate passive protection against infectious agents, including antibiotic-resistant bacteria and viral agents that are difficult to treat.

The *West Nile Virus Antibody (Equine Origin)* from Novartis Animal Vaccines, Inc. is one example of the newest generation of immunoglobulin products. Conditionally licensed by the USDA, it is the only product to provide passive immunity as an aid in the control of disease caused by the West Nile Virus.



Immunoglobulin products have been available since before the advent of antibiotics, and their longevity is testament to their effectiveness.

Serum therapies had been overshadowed by antibiotic treatments until the last few decades, when problems with newly emerged, re-emerged or persistent infectious diseases necessitated the development of new and improved antibody-based therapeutic approaches.¹ In recent years, antibody-based therapies have returned as a first-line therapy for a variety of diverse conditions, including viral infections, inflammatory disorders and certain malignancies.²

Also known as antiserum, antibody or antitoxin, an immunoglobulin product provides immediate protection through artificially acquired passive immunity. When an animal needs immune therapy instantly, immunoglobulins often are the appropriate therapeutic technology.

Immunoglobulins vs. vaccines

As opposed to vaccines, which stimulate an animal's immune system to produce antibodies, an injection of immunoglobulins provides preformed antibodies to neutralize a specific antigen – without challenging the immune system.

A vaccine may take up to three weeks before the host develops effective levels of humoral immunity. Immunoglobulins deliver immediate, short-term protection via antibodies injected directly into the animal. (Some immunoglobulin products are administered orally.)

Because immunoglobulins do not stimulate the animal's immune system to produce its own antibodies, the duration of protection is relatively short. The half-life of immunoglobulins is approximately 21 days. There are certain situations, however, where immunoglobulins are the most viable treatment option.

When to use immunoglobulins

Providing passive immunity via immunoglobulins is commonly used to treat acute infections and as a prophylactic in animals and humans. It also is appropriate to utilize in immune-suppressed situations, when antibiotic resistance is suspected, and in viral disease outbreaks where antibiotics have a limited effect.

Examples of when to use immunoglobulins include:

- **There is a disease outbreak in an animal or herd that has not been vaccinated.**

For example, when an unvaccinated horse is showing signs of illness from exposure to West Nile Virus, it's too late for a vaccine to stimulate the immune system. The new *West Nile Virus Antibody (Equine Origin)* from Novartis Animal Vaccines, Inc. is an immediate source of immunoglobulins and has been conditionally licensed by the U.S. Department of Agriculture (USDA) as an aid in the control of disease caused by West Nile Virus.

- **An animal was vaccinated but still contracts a disease.**

In this case, there are several possibilities. The animal may have been incubating the disease when it was vaccinated, or its immune system was previously compromised by poor nutrition, discomfort, stress, sanitation, etc. The vaccine may have been administered too late, the dosage was inadequate or it was of poor quality. Immunoglobulins can provide the animal with immediate, short-term immunity to the disease challenge.

West Nile Virus Antibody: Targeting the West Nile Virus

One of the newest antibody products on the market provides valuable therapy against one of the most threatening viruses.

To say the West Nile Virus has caused concern in the equine industry is an understatement. In 2002, the virus was found in horses in 40 states. Of the 14,717 equine cases reported, almost one-third died or were euthanized. When a horse contracted the mosquito-borne virus, the only option was to use therapies to alleviate the symptoms.

Novartis Animal Vaccines, Inc. responded to this urgent need by bringing a *West Nile Virus Antibody (Equine Origin)* to the equine industry. The USDA recently issued a conditional license for the product to aid in the control of disease caused by the virus.

The use of the *West Nile Virus Antibody* in horses provides high quality, neutralizing IgG immunoglobulins

immediately upon administration. Cornell University analyzed the *West Nile Virus Antibody* and conducted serum neutralization testing and neutralizing index studies on post-administration serum samples. This research demonstrated a rise in the neutralizing serological antibody to the West Nile Virus following antibody administration.

West Nile Virus Antibody focuses specifically on this virus; it's the only product that provides passive immunity as an aid in the control of disease caused by the West Nile Virus. *West Nile Virus Antibody* allows the actual disease-causing agent to be targeted rather than being limited to symptomatic treatments.

To learn more about the *West Nile Virus Antibody*, contact Novartis Animal Vaccines, Inc. at 1-800-843-3386 or visit www.livestock.novartis.com.

- **In newborn animals not receiving enough high-quality colostrum.** This is an instance where immunoglobulins are used as a preventive treatment. An example would be when the dam wasn't adequately vaccinated, or wasn't vaccinated at the appropriate time to provide ample levels of antibodies in the colostrum. The dam also may be environmentally stressed, immune incompetent or ill, and not producing enough colostrum.

Immunoglobulin production

Disease-specific immunoglobulins are produced by harvesting serum from animals that have been immunized with a specific antigen. The serum is purified, screened and tested to assure sterility, safety and potency. All immunoglobulin products for administration to livestock are licensed and regulated by the USDA.

Effective immunoglobulins provide good protection against the specific antigen, results in minimal reaction and can be safely administered. Anaphylactic reactions to immunoglobulin products are rare, but do occur at slightly higher rates than with vaccines. Symptoms should be treated with epinephrine. For best results, choose immunoglobulins from a reputable, proven manufacturer.

Novartis Animal Vaccines, Inc. continually strives to advance the technology for developing and producing innovative immunoglobulin therapies. This commitment to antibody-based therapies is demonstrated in Novartis' new, state-of-the-art serum production facility in Larchwood, Iowa.

1 Oral HB, et al. Back to the future: antibody-based therapies for the treatment of infectious diseases. *Molecular Biotechnology*. July 2002;21(3):225-39.

2 Casadevall A. Passive antibody therapies: progress and continuing challenges. *Clinical Immunology*. October 1999;93(1):5-15.

