New Drug Approvals

Generic Name (Trade Name—Company) | Uses/Notes
October 18, 2018

Crotalidae Immune F(ab’ )2 (Equine) | Rare Disease Therapeutics announced FDA approval of Crotalidae Immune F(ab’ )2 (Equine), an equine-derived antivenin for treatment of North American rattlesnake bites in adult and pediatric patients.

(Anavip—Rare Disease Therapeutics) | FDA approves new antivenom for rattlesnake bites

CDC has estimated that the U.S. incidence of venomous snake bites is 7,000 to 8,000 per year. Because people seek—and receive—rapid medical intervention, the number of deaths from snake bites is low: about five per year. However, blood clotting disorders can be major complications of a venomous rattlesnake bite, and one of the goals of treatment is to limit the potential incidence of latent coagulopathy. Because this new antivenom lasts longer in the body, it eliminates the need for scheduled maintenance doses.

The antivenom has a long half-life to minimize the likelihood of reemergent venom effects (such as a drop in platelets, prolonged bleeding times, and other abnormal blood clotting tests) that commonly require additional doses of a shorter-acting antivenom.

The most common adverse reactions (>2%) in clinical studies were pruritus, nausea, rash, arthralgia, peripheral edema, myalgias, headache, pain in extremity, vomiting, and erythema.

Warnings and precautions include allergic reactions, especially in patients with known allergies to horse protein. If signs or symptoms of anaphylaxis or hypersensitivity reactions (including urticaria, rash, tightness of the chest, wheezing, hypotension) occur, discontinue immediately, and institute appropriate treatment.

Monitor patients with follow-up visits for signs and symptoms of delayed allergic reactions or serum sickness (rash, fever, myalgia, arthralgia, pruritus, urticarial rash), and treat appropriately if necessary.

Because the product is made from equine plasma, it may carry a risk of transmitting infectious agents (e.g., viruses).