ANITVENIN CROTALIDAE POLYVALENT EQUINE ORIGIN

RATTLERANTIVENIN™

Indications and Usage: Rattler Antivenin is shown to be effective against envenomation in canine, equine, and feline due to North American Crotalidae. Crotalidae refers to the Crotalinae subfamily (commonly named 'Pit Vipers') and includes cottonmouths/water moccasins, copperheads, and rattlesnakes. Rattler Antivenin includes antibodies against, among other Crotalidae, Mohave Rattlesnake Type A which is often considered to be the most lethal rattlesnake due to the presence of highly debilitating neurotoxin A, also known as 'The Mohave Toxin.'
Use of Rattler Antivenin within 24 hours of snakebite neutralizes venom, decreases swelling, minimizes pain, and decreases temperature in canine, equine, and feline patients.

Composition: Rattler Antivenin is a whole-IgG molecule Crotalidae Polyvalent Antivenin. Rattler Antivenin contains antivenom (antibodies) collected from healthy horses immunized against Crotalus atrox (Western Diamondback Rattlesnake), Crotalus adamanteus (Eastern Diamondback Rattlesnake), Crotalus viridis viridis (Prairie Rattlesnake), and Crotalus scutalatus scutulatus (Mohave Rattlesnake Type A). Rattler Antivenin is produced through a manufacturing process that combines antibodies from both hemolytic and neurotoxic venoms, resulting in a unique antivenom matrix. Sodium citrate is used in the manufacturing process. This product does not contain any preservatives. Each serial of Rattler Antivenin must pass release criteria by neutralizing specific units of viperine venom activity in a live murine model.

Dosage and Administration:
Feline: Administer to effect intravenously using a filtered IV set at 2-3 mL/kg/hour.

Canine and Equine: Administer to effect intravenously using a filtered IV set over a 20-60 minute period.

Administration for All Species: This product should be thawed quickly (2-5 minutes) in warm, not hot, water while agitating and should be administered immediately.

Do not allow product to be heated for an extended period (over 10 minutes) at risk of denaturing the product, potentially leading to reactions or impotency. See "Warnings and Precaution" section of this insert for more details.

One to two 50ml doses will be sufficient in most cases regardless of body size (feline, small canine, large canine, equine). Additional doses may be necessary on a case-by-case basis. Factors to consider include the severity of envenomation, type and size of snake, and size of patient (the smaller the body of the victim, the more the venom to blood volume ratio increases).

Administer Rattler Antivenin as is, without reconstitution or dilution. Use entire contents when first opened. Do not mix this product with other fluids. As with any antivenin, additional fluids and supplemental therapies can be used. In case of human exposure, contact a physician.

Restricted to use by or under the direction of a licensed veterinarian.

Canine Age and Species: Rattler Antivenin is recommended for use in canines as young as 8 weeks old. Rattler Antivenin has not been evaluated in pregnant or lactating bitches.

Equine Age and Species: Rattler Antivenin is safe for adult horses. No data is available for pregnant or lactating mares.

Feline Age and Species: The approved age for administration is 12 weeks-of-age or older for felines. No data is available for pregnant or lactating felines. Rattler Antivenin has not been evaluated in pregnant or lactating queens.

Adverse Events, Warnings and Precautions:
If you are unfamiliar with administering Rattler Antivenin, please feel free to contact our technical support team (techsupport@mgbiologics.com or 877-769-2340) to ensure proper procedure is followed. Guidance videos are available on our website, mgbiologics.com.

Do not place in an incubator. Administer product at body temperature, warm to body temperature just prior to administration to minimize the risk of denaturing the antivenin due to extended heat exposure. Extended heat exposure can cause product impotency or, in rare cases, anaphylaxis.

Every reasonable precaution has been taken to safeguard this product. There is always the possibility, while rare, of adverse events. Hypersensitivity reactions could occur in all species. This product has not been processed by heating or treating with ionizing radiation and may be capable of spreading disease.

A condition referred to as equine serum hepatitis, or Theiler's disease, has been linked to the usage of products containing equine serum or plasma. Current research has implicated Equine Parvovirus-Hepatitis as a potential causative agent for equine serum hepatitis, or Theiler's Disease. This product has been tested and is Equine Parvovirus-Hepatitis free.

Canine Adverse Events, Warnings and Precautions: *Always check patient history for previous equine protein exposure or previous reaction to foreign protein biologics.* The risk of anaphylaxis may increase if the patient has a history of intravenous infusion of equine blood products, such as, but not limited to antiserums like tetanus antitoxin or other antivenin administration. There is no guaranteed time frame to wait between equine protein exposures to prevent an adverse reaction. Anti-equine immunoglobulins are created by the canine in response to receiving equine products and can cause adverse events with subsequent equine protein exposures if given at peak circulation of these anti-equine immunoglobulins. Patients may have a higher risk of adverse events if they have received equine protein products, including antivenin, in the past year. Use professional judgment. Administer slowly for the first ten minutes and monitor for signs of anaphylaxis (hypotension, respiratory distress, vomiting, diarrhea, angioedema, urticaria). If no immediate adverse response occurs, administration may resume at an IV fluid administration rate appropriate for the patient. Use professional judgment for each individual case; weigh the benefits of continuing antivenin treatment depending on case severity and history of the patient. In case of anaphylaxis, give epinephrine.

In rare cases, serum sickness (a type III hypersensitive reaction) may present 10-14 days after administration. This condition is unpredictable but should be treated with corticosteroids and antihistamines; it is not life threatening. Typical signs are fever, uticaria, lethargy, swollen lymph nodes, and painful joints. This is an underreported condition and should be reported to the manufacturer if this occurs. While the literature is silent in regards to canine serum sickness rates, this condition is well documented in human envenomation treatments. Based on industry feedback, we would expect <0.05% patients receiving this product to experience serum sickness post use of this product.

Equine Adverse Events, Warnings and Precautions: Administer slowly for the first ten minutes and monitor for signs of anaphylaxis (hypotension, respiratory distress, angioedema, urticaria). If this occurs, discontinue use for 5-10 minutes, then resume at a slower rate of infusion. If adverse reactions persist, discontinue use.

Feline Adverse Events, Warnings, and Precautions: Administer slowly for the first ten minutes and monitor for signs of hypersensitivity (vocalizing, facial redness, salivating, and agitations) and anaphylaxis (hypotension, respiratory distress, vomiting, diarrhea, and cardiac arrest). If no immediate adverse response occurs, administer at a rate of 2-3 mL/kg/hr. Use Professional judgment for each individual case; weigh the benefits of continuing antivenin treatment depending on case severity and history of the patient. In case of anaphylaxis, give epinephrine.

General Information: Approximately 1200 doses of Rattler Antivenin were distributed to 198 veterinarians with only 0.76% reporting adverse events in canine. Of these adverse events, clinical signs included uticaria, vomiting, diarrhea, hypotension, and change in respiratory rate). No delayed hypersensitivity or volume overload occurred in these documented cases. No equine adverse events were reported. While these results show a high safety rate, there is always a risk of an adverse event with any blood product.

Detailed clinical evaluation of Rattler Antivenin was performed by 17 veterinary clinics on 132 envenomated dogs and 34 envenomated horses. Licensed veterinarians at these clinics reported successful results with Rattler Antivenin in canine and equine patients presenting with mild to severe symptoms of envenomation at time of treatment. Of 132 canine patients, 93% survived envenomation following treatment with Rattler Antivenin. Of 34 equine patients, 100% survived envenomation following treatment with Rattler Antivenin.

Store frozen below -5°C (23°F) until use.

Rattler Antivenin has passed QA purity tests and should not be reused or refrozen once opened.

As this product does not include any harmful preservatives, unused portions may be safely discarded in the trash.

This package is not returnable for credit or exchange.

Join our pursuit of pharmacovigilance by reporting all adverse events to (877)-769-2340 or techsupport@mgbiologics.com.

Made in the USA.

VLN 614 / PCN 6101.01

V. 3-2022

Mg Biologics

VLN 614 / V. 3-2022
(877) 769-2340 mgbiologics.com
2366 270th St. Ames, IA 50014