RARE DISEASE THERAPEUTICS, INC.

APRIL 1, 2021

IMPORTANT PRESCRIBING INFORMATION

Subject:	**Introducing an Expanded Indication for ANAVIP®** **ANAVIP [crotalidae immune F(ab')$_2$ (equine)] is an equine-derived antivenin indicated for the management of adult and pediatric patients with North American Pit Viper envenomation.**

Dear Health Care Provider:

The purpose of this letter is to introduce an expanded indication for ANAVIP. We have been granted an expanded indication to include all North American Pit Viper envenomations. This expanded indication now includes rattlesnake, copperhead, and cottonmouth/water moccasin envenomations.

Dosage and Administration

Administer ANAVIP as soon as possible after pit viper bite in patients who develop any signs of envenomation (e.g., local injury, coagulation abnormality, or systemic signs of envenomation).

The amount of antivenin required to treat a snake bitten patient is highly variable owing in part to the venom burden, the potency of the venom and the time to health care presentation. Use supportive measures to treat certain manifestations of pit viper envenomation, such as pain, swelling, hypotension, and wound infection. Contact the local poison control centers for additional individual treatment advice.

Prior to initiating treatment, perform laboratory analyses, including complete blood count, platelet count, PT, PTT, serum fibrinogen level, and routine serum chemistries. Repeat testing at regular intervals to gauge response to therapy and anticipate additional dosing.

Dose	Number of Vials	Infusion Rate
Initial Dose	10 vials	Infuse intravenously over 60 minutes.
Additional dose(s) to achieve initial control	10 vials (as needed)	Infuse intravenously over 60 minutes.
Observation and late dosing	4 vials	Infuse intravenously over 60 minutes.

Prescriber Action
The dosing remains unchanged.

2550 Meridian Blvd., Suite 150 • Franklin, Tennessee • Telephone: 615/399-0700 • Fax: 615/399-1217 • www.raretx.com

Counsel patients about the risks and benefits of ANAVIP, including:

- Advise patients to contact their physician immediately if they experience unusual bruising or bleeding (e.g., nosebleeds, excessive bleeding after brushing teeth, the appearance of blood in stools or urine, excessive menstrual bleeding, petechiae, excessive bruising or persistent oozing from superficial injuries) after hospital discharge.
- Advise patients to contact their physician immediately if they experience any signs and symptoms of delayed allergic reactions or serum sickness (e.g., rash, fever, myalgias, arthralgia, pruritus, urticaria) after hospital discharge.

Reporting Adverse Events
Health care providers and patients are encouraged to report adverse reactions in patients taking ANAVIP at 1-844-472-7389. You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

You may also contact our medical information department at 1-844-472-7389 if you have any questions about the information contained in this letter or the safe and effective use of ANAVIP.

This letter is not intended as a complete description of the benefits and risks related to the use of ANAVIP. Please refer to the enclosed full prescribing information.

For additional information, please call Rare Disease Therapeutics, Inc. at 1-844-472-7389 or visit www.anavip.com.

Sincerely,

Jude T. McNally
President
Rare Disease Therapeutics, Inc.

Enclosure(s): ANAVIP Full Prescribing Information

SCAN ME — RDT Homepage

SCAN ME — ANAVIP Homepage

SCAN ME — ANAVIP Full Prescribing Information

SCAN ME — ANAVIP Contact Us

SCAN ME — FDA Adverse Event Portal

2550 Meridian Blvd., Suite 150 • Franklin, Tennessee • Telephone: 615/399-0700 • Fax: 615/399-1217 • www.raretx.com