

CroFab[®] Crotalidae Polyvalent Immune Fab (Ovine)

A SAFE, EFFECTIVE WAY TO TREAT CROTALID SNAKEBITES IN THE EMERGENCY SETTING

- Prepared from affinity-purified, sheep-derived Fab fragments.
- No cases of anaphylaxis were reported in pre-marketing clinical trials (n=42).
- Serum sickness was reported in 1 out of 42 patients.
- Indicated for the management of patients with minimal to moderate North American crotalid envenomation (this class may include rattlesnakes, water moccasins and copperheads).
- Poison Control Centers nationwide recommend stocking enough antivenom to treat at least one patient.

DOSING



Recommended Initial Dose



4 to 6 vials infused IV over 60 minutes. Infuse initial dose slowly over the first 10 minutes at a 25-50mL/hr rate. Repeat if necessary, until initial control is achieved. Initial control is defined as complete arrest of local manifestations and normalization of coagulation test results and systemic signs.

After Initial Control is Achieved



6 hours



12 hours



18 hours

2 vials every 6 hours for up to 18 hours (a total of 3 additional doses).

Follow-up Dose (If Necessary)



2 vials, as deemed necessary by the treating physician, based on patient's clinical course.

- In clinical trials, a median of 12 vials was used; the range was 3 to 18 vials.
- Each vial of CroFab[®] Crotalidae Polyvalent Immune Fab (Ovine) should be reconstituted with 10mL of Sterile Water for Injection, USP (diluent not included) and gently swirled until reconstituted.* Reconstitution time is approximately 10-30 minutes.
- The reconstituted vials (ALL of the 4 to 6 vials - depending on your initial dose) should be added to 250mL of 0.9% sodium chloride, USP for further dilution and mixed with continuous gentle swirling.* Repeat this procedure for follow-up doses.
- CroFab[®] is NOT a weight based product. No dosage adjustment for age or weight should be made.
- No skin testing is required.
- Reconstituted and diluted CroFab[®] should be used within 4 hours.

ADVERSE REACTIONS, WARNINGS AND CONTRAINDICATIONS**

- Majority of adverse reactions to CroFab[®] were mild to moderate in severity.
- The most common adverse events were urticaria and rash.
- One patient experienced recurrent coagulopathy due to envenomation. Two patients experienced severe allergic reactions (severe hives and a severe rash and pruritus) following treatment. All patients made a complete recovery.
- Recurrent coagulopathy may persist for 1 to 2 weeks or more.
- One patient discontinued CroFab[®] therapy due to an allergic reaction.
- Patients with allergies to papain, chymopapain, other papaya extracts, or the pineapple enzyme bromelain may also be at risk for an allergic reaction to CroFab[®].

Ensure that your inventory levels for CroFab® Crotalidae Polyvalent Immune Fab (Ovine) are in-line with the recommended guidelines for stocking emergency antidotes.

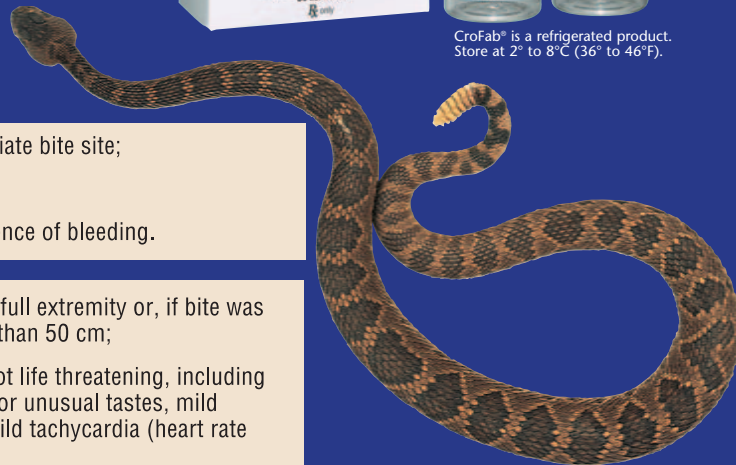
To date, there are no clinical data supporting the efficacy of CroFab® in patients presenting with severe envenomation.

Definition of Minimal, Moderate and Severe Envenomation in Clinical Studies of CroFab®

Envenomation Category	Definition
Minimal	<p><u>Swelling, pain, and ecchymosis</u> limited to the immediate bite site;</p> <p><u>Systemic signs and symptoms</u> absent;</p> <p><u>Coagulation parameters</u> normal with no clinical evidence of bleeding.</p>
Moderate	<p><u>Swelling, pain, and ecchymosis</u> involving less than a full extremity or, if bite was sustained on the trunk, head or neck, extending less than 50 cm;</p> <p><u>Systemic signs and symptoms</u> may be present but not life threatening, including but not limited to nausea, vomiting, oral paresthesia or unusual tastes, mild hypotension (systolic blood pressure >90 mmHg), mild tachycardia (heart rate <150), and tachypnea;</p> <p><u>Coagulation parameters</u> may be abnormal, but no clinical evidence of bleeding present. Minor hematuria, gum bleeding and nosebleeds are allowed if they are not considered severe in the investigator's judgment.</p>
Severe	<p><u>Swelling, pain, and ecchymosis</u> involving more than an entire extremity or threatening the airway;</p> <p><u>Systemic signs and symptoms</u> are markedly abnormal, including severe alteration of mental status, severe hypotension, severe tachycardia, tachypnea, or respiratory insufficiency;</p> <p><u>Coagulation parameters</u> are abnormal, with serious bleeding or severe threat of bleeding.</p>



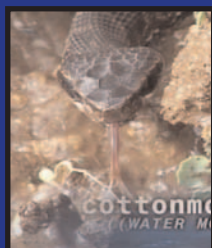
CroFab® is a refrigerated product. Store at 2° to 8°C (36° to 46°F).



* A CroFab® Training Video exhibiting the recommended reconstitution method is available at no cost through your local representative, or by calling Fougera® Customer Service (800) 645-9833. Please contact your local representative for more information or educational material related to CroFab® treatment.

** For additional events, precautions or warnings, please refer to the attached full prescribing information.

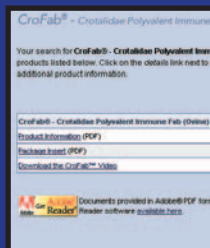
The support you need from one of the most trusted names in hospitals.



CroFab® Training Video Available



Dedicated Sales Support Staff And Customer Service



Downloadable Web Info Including Pricing At www.fougera.com



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MAKE NO COMPROMISES.®

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Distributed by Fougera® and Savage Laboratories®, both divisions of ALTANA Inc, Melville, NY 11747