

**A safe, effective method for minimal or moderate North American  
crotalid snakebite treatment in the emergency setting.**



**Are you prepared  
should danger**

**strike**  
unexpectedly?

**CroFab<sup>®</sup>**

**Crotalidae Polyvalent  
Immune Fab (Ovine)**

Please see Important Safety and Full Prescribing Information inside.

# CroFab<sup>®</sup> Crotalidae Polyvalent Immune Fab (Ovine)

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

- CroFab<sup>®</sup> Crotalidae Polyvalent Immune Fab (Ovine) is indicated for the management of patients with minimal or moderate North American crotalid envenomation (see Table 3 from package insert on next page). The term crotalid is used to describe the Crotalinae subfamily (formerly known as Crotalidae) of venomous snakes which includes rattlesnakes, copperheads and cottonmouths/water moccasins. Early use of CroFab<sup>®</sup> (within 6 hours of snakebite) is advised to prevent clinical deterioration and the occurrence of systemic coagulation abnormalities.
- 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.
- 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.

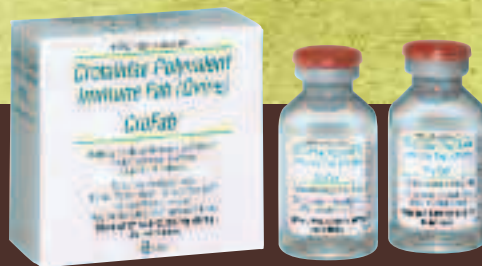
- In clinical trials, a median of 12 vials was used; the range was 3 to 18 vials.
- Each vial of CroFab<sup>®</sup> Crotalidae Polyvalent Immune Fab (Ovine) should be reconstituted with 10mL of Sterile Water for Injection, USP (diluent not included) and gently swirled until reconstituted.\* Reconstitution 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<sup>®</sup> 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<sup>®</sup> should be used within 4 hours.

### IMPORTANT SAFETY INFORMATION\*\*\*

The most common adverse events reported in clinical studies were mild or moderate reactions involving the skin and appendages (primarily urticaria, rash or pruritus), which occurred in 14 out of 42 patients. Three patients experienced a serious adverse event. Two patients had a severe allergic reaction (severe hives and a severe rash and pruritus) following treatment. One patient had a recurrent coagulopathy due to envenomation, which required re-hospitalization and additional antivenin administration. In clinical trials, recurrent coagulopathy (the return of a coagulation abnormality after it has been successfully treated with antivenin), characterized by decreased fibrinogen, decreased platelets and elevated prothrombin time, occurred in approximately half of the patients studied. Recurrent coagulopathy may persist for one to two weeks or more. One patient discontinued CroFab<sup>®</sup> 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<sup>®</sup>.



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

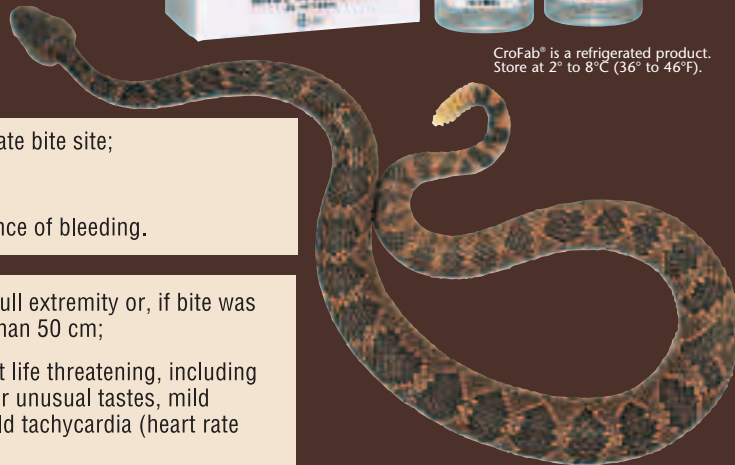


CroFab® is a refrigerated product. Store at 2° to 8°C (36° to 46°F).

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

Table 3

Envenomation Category	Definition
<b>Minimal</b>	<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>
<b>Moderate</b>	<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 &lt;90 mmHg), mild tachycardia (heart rate &lt;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>
<b>Severe*</b>	<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>



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

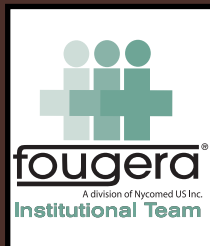
\*\*A CroFab® Training Video exhibiting the recommended reconstitution method is available at no cost through your local representative, or by calling Fougera® Customer Service (800) 645-9833. Please contact your local representative for more information or educational material related to CroFab® treatment.

\*\*\* 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](http://www.fougera.com)



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Bar Coded Packaging For Inventory, Safety And Billing Accuracy

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