CroFab®
crotalidae polyvalent immune fab (ovine)

It's more than a pit viper envenomation

Stop the progression

Be prepared for North American pit viper envenomation. CroFab®:

- Can stop toxic progression for most patients[1]
- Treats venomous bites from North American pit vipers, regardless of severity[1]
- Can improve clinical outcomes with early administration[1,2]
- Has a well-established safety profile[1,3]

Indication

CroFab® Crotalidae Polyvalent Immune Fab (Ovine) is indicated for the management of patients with North American crotalid envenomation. The term crotalid is used to describe the Crotalinae subfamily (formerly known as Crotalidae) of venomous snakes that includes rattlesnakes, copperheads, and cottonmouths/water moccasins. Early use of CroFab® (within 6 hours of snakebite) is advised to prevent clinical deterioration and the occurrence of systemic coagulation abnormalities.

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 rehospitalization 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 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®.

Please click to see full prescribing information, including events, precautions, or warnings.

DIGIFab
digoxin immune fab (ovine)

Life-threatening digoxin toxicity can be difficult to recognize[4]

Your treatment choice should be clear

In cases of life-threatening or potentially life-threatening digoxin toxicity or overdose, DigiFab®:

- Rapidly binds and neutralizes digoxin with measurable results[5]
- Has a well-established safety profile[5]
- Offers flexible dosing, specific to the clinical situation[5]

Indication

DigiFab® Digoxin Immune Fab (Ovine) is indicated for the treatment of patients with life-threatening or potentially life-threatening digoxin toxicity or overdose. DigiFab® is indicated for the same conditions as Digibind®*. Clinical claims, indications, and usage of DigiFab® are identical to Digibind®. Neither product is indicated for milder cases of digitalis toxicity.

Important Safety Information

Based on experience with Digibind®*, the following adverse reactions could occur with the use of DigiFab®:

Exacerbation of low cardiac output states and congestive heart failure due to the withdrawal of the inotropic effect of digitalis; hypokalemia due to reactivation of the sodium-potassium ATPase; rapid ventricular response in patients with atrial fibrillation due to the withdrawal of the effects of digitalis on the atrioventricular node; and rare allergic reactions. Patients with allergies to papain, chymopapain, other papaya extracts, or the pineapple enzyme bromelain may be at risk for an allergic reaction to DigiFab®. DigiFab® is an animal protein; monitor for delayed allergic reactions and hypersensitivity.

Suicidal ingestion may involve more than 1 drug. Toxic effects of other drugs or poisons should not be overlooked.

In the clinical trials of DigiFab®, 6 of 15 patients in the digoxin overdose study had a total of 17 adverse experiences; most were mild to moderate in nature and all were deemed "remotely associated" with DigiFab®. Three events were deemed "severe"; all occurred in 1 patient and consisted of the following: pulmonary edema, bilateral

pleural effusion, and renal failure. After reviewing the case, it was determined that these events were likely due to the loss of digoxin inotropic support in combination with the patient's underlying medical condition. Of 8 healthy volunteers who received DigiFab®, only 2 experienced an adverse reaction that was considered to be associated with DigiFab®. The reactions were 1 episode of phlebitis of the infusion vein and 1 episode of moderate postural hypotension, which became mild prior to resolving.

*Digibind® is a registered trademark of GlaxoSmithKline. Neither GlaxoSmithKline nor Digibind® are related or affiliated with BTG International Inc.

Please click to see full prescribing information, including events, precautions, or warnings.

Order now through Cardinal Health:

- NDC# 50633-110-12
- Item Number 4348470

www.crofab.com

24-hour Medical Information: 1-877-377-3784
Customer Service: 1-877-852-8542 (Voice), 1-877-852-8545 (Fax)

Order now through Cardinal Health:

- NDC# 50633-120-11
- Item Number 4348405

www.digifab.us.com

24-hour Medical Information: 1-877-377-3784
Customer Service: 1-877-852-8542 (Voice), 1-877-852-8545 (Fax)

References

1. CroFab® [prescribing information]. Brentwood, TN: Protherics Inc; September 2010.
2. Dart RC, Seifert SA, Boyer LV, et al. A randomized multicenter trial of crotalinae polyvalent immune Fab (ovine) antivenom for the treatment for crotaline snakebite in the United States. *Arch Intern Med* 2001;161:2030-2036.
3. Cannon R, Ruha A-M, Kashani J. Acute hypersensitivity reactions associated with administration of crotalidae polyvalent immune Fab antivenom. *Ann Emerg Med*. 2008;51:407-411.
4. Ma G, Brady WJ, Pollack M, Chan TC. Electrocardiographic manifestations: digitalis toxicity. *J Emerg Med*. 2001;20:145-152.
5. DigiFab® [prescribing information]. Brentwood, TN: Protherics Inc; September 2010.

www.crofab.com
www.digifab.us.com

24-hour Medical Information: 1-877-377-3784
Customer Service: 1-877-852-8542 (Voice), 1-877-852-8545 (Fax)

BTG
Because people depend on us