Dosing Guide for DIGIFab,

THE Antidote for Digoxin Toxicity[1-3]

DIGIFab®
digoxin immune fab (ovine)

Appropriate Dosing Neutralizes Digoxin[1]

DIGIFab dosing varies according to clinical condition and amount of digoxin to be neutralized.

- Each vial of 40 mg purified digoxin-specific Fab binds approximately 0.5 mg digoxin.

For patients with acute or chronic toxicity from a known or estimated amount of digoxin, use the DIGIFab dose calculator at **DIGIFab-Dose.health**

For complete dosing and administration information, please see full Prescribing Information.

INDICATIONS AND USAGE

DIGIFab is indicated for the treatment of patients with life-threatening or potentially life-threatening digoxin toxicity or overdose, including:

- Known suicidal or accidental consumption of fatal doses of digoxin: 10 mg or more of digoxin in healthy adults, or 4 mg (or more than 0.1 mg/kg) in healthy children, or ingestion of an amount that can cause steady-state serum concentrations of ≥10 ng/mL;
- Chronic ingestions causing steady-state serum digoxin concentrations >6 ng/mL in adults or 4 ng/mL in children;
- Manifestations of life-threatening toxicity of digoxin overdose such as severe ventricular arrhythmias, progressive bradycardia, and second or third degree heart block not responsive to atropine, serum potassium levels exceeding 5.5 mEq/L in adults or 6 mEq/L in children with rapidly progressive signs and symptoms of digoxin toxicity.

Please see Important Safety Information throughout and full Prescribing Information.

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Appropriate Dosing Neutralizes Digoxin[1]

Chronic toxicity, known serum digoxin level

DIGIFab Dose = $\frac{\textbf{Serum digoxin concentration}\ (\text{ng/mL}) \times \textbf{weight}\ (\text{kg})}{\textbf{100}}$

- For cases of chronic toxicity where serum digoxin levels are unknown, administer 6 vials (240 mg) in adults and children ≥20 kg and 1 vial (40 mg) in infants and children <20 kg.

Use the DIGIFab dose calculator at **DIGIFab-Dose.health**

IMPORTANT SAFETY INFORMATION

Warnings and Precautions

General

Suicidal ingestion may result from more than one drug. Consider toxic effects of other drugs or poisons in cases where signs and symptoms of digitalis toxicity are not relieved by administration of DIGIFab.

Rapid drop in serum potassium concentration may occur after treatment. Monitor frequently.

Patients with poor cardiac function may deteriorate secondary to the withdrawal of the inotropic action of digoxin by DIGIFab. Monitor frequently and provide additional inotropic support if needed. Postpone re-digitalization, if possible, until the Fab fragments have been eliminated; this may require several days or a week or longer in patients with impaired renal function.

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Acute ingestion, known amount*

DIGIFab Dose = $\frac{\textbf{Amount ingested}^{\dagger}\ (\text{mg}) \times \textbf{0.8}}{\textbf{0.5 mg}}$

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

†Total body load for digoxin tablets is approximately equal to the amount ingested (in mg) x 0.8 (bioavailability of the tablet preparation).

- For toxicity due to acute ingestion of unknown amounts of digoxin, administer 20 vials of DIGIFab (800 mg).
  - Monitor for volume overload in small (<20 kg) children.
  - Initiate with 10 vials followed by an additional 10 vials, if needed, to avoid a febrile reaction.

Use the DIGIFab dose calculator at **DIGIFab-Dose.health**

IMPORTANT SAFETY INFORMATION

Warnings and Precautions

Hypersensitivity Reactions

Anaphylaxis and hypersensitivity reactions are possible. Carefully monitor patients for signs and symptoms of an acute allergic reaction and if one occurs, stop the infusion and treat immediately with appropriate emergency medical care.

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Preparation and Administration of DIGIFab[1]

Use and Storage

- Each vial of DIGIFab contains 40 mg of digoxin immune Fab protein and is intended for one-time use only.
- The reconstituted product should be used promptly. If not used immediately, store under refrigeration at 2° to 8°C (36° to 46°F) for up to 4 hours.

Reconstitution

1 Reconstitute each vial of DIGIFab with 4 mL Sterile Water for Injection USP.

2 Gently mix to obtain a solution containing approximately 10 mg/mL digoxin immune Fab protein.

Visually inspect reconstituted vials for particulate matter and discoloration prior to administration, whenever solution and container permit.

3 Add the reconstituted product to an appropriate volume of 0.9% sodium chloride for injection.

IMPORTANT SAFETY INFORMATION

Warnings and Precautions

Hypersensitivity Reactions

Patients with known allergies to sheep protein or those who have previously received intact ovine antibodies or Fab are particularly at risk for an anaphylactic reaction.

Please see additional Important Safety Information throughout and full Prescribing Information.

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Preparation and Administration of DIGIFab[1]

Infusion

Administer slowly as an intravenous infusion over at least 30 minutes. If infusion rate–related reactions occur (eg, hypotension, wheezing, urticaria), the infusion should be stopped and restarted at a slower rate.

If cardiac arrest is imminent, DIGIFab can be given by bolus injection. With bolus injection, an increased incidence of infusion-related reactions may be expected.

To learn more about DIGIFab and potentially life-threatening digoxin toxicity, visit **DIGIFab.health**

IMPORTANT SAFETY INFORMATION

Warnings and Precautions

Hypersensitivity Reactions

Do not administer DIGIFab to patients with a known history of hypersensitivity to papaya or papain unless the benefits outweigh the risks and appropriate management for anaphylactic reactions is readily available.

Use of DIGIFab in Renal Failure

The elimination half-life of DIGIFab in renal failure has not been clearly defined. Monitor patients with severe renal failure who receive DIGIFab for a prolonged period for possible recurrence of toxicity. Monitoring of free (unbound) digoxin concentrations after the administration may be appropriate.

IMPORTANT SAFETY INFORMATION

Warnings and Precautions

Laboratory Tests

DIGIFab may interfere with digitalis immunoassay measurements. Thus, standard serum digoxin concentration measurements may be clinically misleading until the Fab fragments are eliminated from the body. This may take several days or a week or more in patients with markedly impaired renal function. If possible, obtain serum digoxin samples before DIGIFab administration to establish the level of serum digoxin at the time of diagnosis.

The total serum digoxin concentration may rise precipitously following administration of DIGIFab, but this will be almost entirely bound to the Fab fragment and not able to react with receptors in the body.

Adverse Reactions

The most common adverse reactions (>7%) related to DIGIFab administration are worsening congestive heart failure (13%), hypokalemia (13%), and worsening atrial fibrillation (7%).

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References: 1. DIGIFab Digoxin Immune Fab (ovine) [package insert]. West Conshohocken, PA: BTG International Inc.; 2017. **2.** Dart RC et al. *Ann Emerg Med.* 2018;71(3):314-325. **3.** Levine MD, O'Connor A. UpToDate. Updated April 2020. Accessed October 2, 2020. https://www.uptodate.com/contents/digitalis-cardiac-glycoside-poisoning?search=digitaliscardiac-glycoside poisoning&source=search_result&selectedTitle=2~73&usage_type=default&display_rank=2

BTG Pharmaceuticals a SERB company

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Full Prescribing Information

Please see additional Important Safety Information throughout and full Prescribing Information.