

## DigiFAB®

<b>CAUTION: High Administration Risk Rating</b>	
<b>Form &amp; Storage</b>	40mg of digoxin immune Fab (ovine) protein powder for solution for injection <span style="float: right; background-color: #3f51b5; color: white; padding: 2px;">Store in a refrigerator at 2–8°C</span>
<b>Reconstitution</b>	Reconstitute the contents of each vial with 4mL of water for injections by gentle mixing to produce a protein concentration of 10mg/mL. The reconstituted solution should be a clear to slightly opalescent, colourless to pale-yellow solution.
<b>Compatibility &amp; Stability</b>	Sodium Chloride 0.9%
<b>Administration</b>	<p><b><u>IV Injection</u></b> If cardiac arrest is imminent, digoxin immune Fab may be administered by IV injection over 3-5 minutes, but this method of administration is not recommended since it may be associated with increased risk of adverse effects (e.g. allergic reactions).</p> <p><b><u>IV Infusion</u></b> Withdraw the contents from the required number of vials and add to a convenient volume of sodium chloride 0.9% (250-500mL). Use a <u>0.22 micron membrane filter</u> to remove any incompletely dissolved aggregates of DigiFab®. Administer as an IV infusion over 30 minutes using an infusion pump.</p> <p style="text-align: center; background-color: #ffe0b2;"><b>Refer to Protocol for the administration of DigiFAB® to calculate dose</b></p>
<b>Monitoring</b>	<ul style="list-style-type: none"> <li>Monitor temperature and blood pressure. Continuous ECG monitoring is required for at least 24 hours after administration</li> <li>Monitor the serum potassium concentration as DigiFab® may result in significant hypokalaemia.</li> <li>DigiFAB® may interfere with digoxin immunoassay measurements. Thus, standard serum digoxin concentration measurements may be clinically misleading until the Fab fragments are eliminated from the body.</li> </ul>
<b>Additional Information</b>	<ul style="list-style-type: none"> <li>Use of DigiFab® may worsen congestive heart failure &amp; atrial fibrillation</li> <li>Doses should ordinarily be rounded up to the next whole vial.</li> </ul>

**Information relates to DigiFab® manufactured by Protherics**