Prescribing Information for DIGIFab® 40 mg/vial digoxin immune Fab, powder for solution for infusion. Please consult Summary of Product Characteristics (SmPC) before prescribing.

Presentation: Powder for solution for infusion. Each glass vial of DIGIFAB contains 40mg of digoxin immune Fab (Ovine) protein as a sterile lyophilized, off white powder.

Indication: The treatment of known (or strongly suspected) life-threatening digoxin toxicity or cardiac glycoside poisoning associated with ventricular arrhythmias or bradyarrhythmias unresponsive to atropine where measures beyond withdrawal of digoxin or cardiac glycosides and correction of serum electrolyte abnormalities are considered necessary.

Dosage: Discuss management of patients with digoxin toxicity or cardiac glycoside poisoning with TOXBASE at**: +44 344 892 0111** (in Ireland NPIC (01) 809 2566) and/or refer to https://www.toxbase.org/. The dose of DIGIFAB depends on the clinical situation and on whether plasma digoxin concentration is available.

For poisoning from pharmaceutical digoxin or from cardiac glycosides other than pharmaceutical digoxin: ***Cardiac arrest due to digoxin toxicity or cardiac glycosides:*** Urgently administer digoxin-specific FAB fragments as an IV bolus, further doses may be required if an adequate clinical response is not seen after 30 minutes:

Weight (adult and children)	DigiFab dose (each vial should be reconstituted with 4 mL of sterile water by gentle mixing)
>40 kg	5 vials (200 mg)
20-40 kg	2 vials (80 mg)
≤20 kg	1 vial (40 mg)

Severe bradyarrhythmia or life-threatening ventricular arrhythmia or severe hyperkalaemia (e.g. K+ greater than 6.5 mmol/L) resistant to adequate rehydration and conventional treatments due to poisoning from digoxin: (NOTE: this applies to acute digoxin overdose on top of usual therapy, acute overdose and toxicity from chronic therapy)

-*When digoxin concentration is available* (measured 6 hours after overdose, unless urgently indicated in patient with arrhythmia), number of vials = (serum digoxin concentration (ng/mL) X weight (kg)) ÷ 200. Round up to the nearest vial.

-*When only ingested dose is available*, number of vials = amount of digoxin ingested (mg) X 0.8. Round up to the nearest vial.

Severe bradyarrhythmia or life-threatening ventricular arrhythmia or severe hyperkalaemia (e.g. K+ greater than 6.5 mmol/L) resistant to adequate rehydration and conventional treatments due to poisoning from cardiac glycosides other than digoxin: urgently administer digoxin-specific antibody FAB fragments as an IV bolus; repeat doses after 15 – 30 minutes if response is inadequate:

Weight (adult and children)	DigiFab dose (each vial should be reconstituted with 4 mL of sterile water by gentle mixing)
>40 kg	2 vials (80 mg)
≤40 kg	1 vials (40 mg)

Please refer to the SmPC for full dosing and administration information, including reversal failure.

Paediatric population: Data on the safety and efficacy of DIGIFAB in children are limited. Small children < 20 kg should be monitored for volume overload.

Administration: DIGIFAB should be reconstituted prior to administration. Depending upon clinical circumstances, the final solution of reconstituted and diluted DIGIFAB may be infused intravenously over a 30-minute period. Each vial should be reconstituted with 4 mL of sterile Water for Injection by gentle mixing. This produces an approximately isosmotic solution with a protein concentration of 10 mg/mL that may be diluted further to any convenient volume with sterile saline (0.9% NaCl) suitable for infusion.

Contraindications: Hypersensitivity to active ingredient or excipients.

Precautions and Warnings: In order to improve traceability of biological medicinal products, the name and the batch number of the administered product should be clearly recorded. ***Infusion-related reactions or hypersensitivity*** reactions are possible. Monitor for anaphylaxis/acute allergic reaction. Medical support must be readily available when DIGIFab is administered. If an anaphylactic reaction occurs during an infusion, then administration of DIGIFAB must be stopped immediately. Repeat dosing may give rise to an anaphylactic reaction and must only be done when the clinical benefit outweighs the risk. Likelihood of an allergic reaction may be higher in subjects who are allergic to sheep-derived proteins (as may be found in cheese and meats), papain (papain shares allergenic structures with chymopapain and other papaya extracts, bromelain found in pineapple, dust mite allergens and latex allergens) and alpha-gal or have been diagnosed with alpha-gal syndrome (a type of food allergy to red meat and products made from mammals). ***General management:*** Patients should have continuous ECG, temperature, blood pressure and potassium concentration monitoring during and for at least 24 hours after administration. Patients previously dependent on the inotropism of digoxin may develop signs of heart failure when treated with DIGIFAB. Suicidal ingestion may involve more than one drug. Toxic effects of other drugs or poisons should not be overlooked. If, after several hours, toxicity has not adequately reversed or appears to recur, re-administration of DIGIFAB at a dose guided by clinical judgement may be required. There is no information on re-administration of DIGIFAB for a second (or more) episode of digoxin toxicity or cardiac glycoside poisoning**.** There are no data on repeated dosing of DIGIFAB. ***DIGIFAB may interfere with digoxin immunoassay measurements***. Therefore, serum digoxin measurements may be clinically misleading until the Fab fragments are eliminated from the body. This may take several days or more than a week in patients with impaired renal function. Digoxin assay kits may not be able to measure accurately digoxin concentrations greater than 5 ng/mL (6.4 mmol/L) therefore caution is needed above these figures to calculate the dose of DIGIFAB required. ***Impaired Renal and hepatic function:*** It may be expected that excretion of the Fab-digoxin complexes from the body is slowed in the presence of renal impairment and that digoxin may be released after some days from retained Fab-digoxin complexes. There is no information on the use of DIGIFAB in subjects with hepatic impairment. Please consult SmPC for further information on special warnings and precautions for use.

Interactions: No interaction studies have been performed.

Pregnancy, lactation and fertility: No data in pregnancy; DIGIFab should be considered only if the expected clinical benefit of treatment to the mother outweighs any possible risk to the developing foetus. It is not known whether DIGIFab is excreted in human milk. Risk to the breastfeeding child cannot be excluded. Breastfeeding should be discontinued during treatment with DIGIFAB. There are no fertility data.

Side effects: C*ommon*: hypersensitivity reactions, hypo and hyperkalaemia; headache, confusion; nausea, vomiting, diarrhoea, constipation, abdominal distension; worsening of cardiac failure, chest pain, hypotension, orthostatic hypotension; flu-like illness; renal failure; fatigue; infusion site phlebitis. Adverse reactions may occur up to 14 days after the infusion has been administered. Exacerbation of low cardiac output states and congestive heart failure or a rapid ventricular response in patients with atrial fibrillation may occur owing to withdrawal of effect of digoxin. Please consult SmPC in relation to other adverse reactions.

Overdose: No case of overdose has been reported in adults or paediatrics.

Effects on ability to drive and use machines: No studies on the effects on the ability to drive and use machines have been performed

List of excipients: Sodium acetate, acetic acid, mannitol

Incompatibilities: In the absence of compatibility studies, this medicinal product must not be mixed with other medicinal products.

Shelf life and storage: 3 years. From a microbiological point of view, the product should be used immediately after reconstitution. Store

between 2 and 8°C. Do not freeze. Keep vial in outer carton in order to protect from light.

Disposal and handling precautions: Any unused product should be disposed of in accordance with local requirements. For single use only. Use immediately after reconstitution. The reconstituted solution should be a clear to slightly opalescent, colourless to pale yellow solution.

Legal classification: POM

NHS List Price: £750

United Kingdom Marketing Authorisation Number: PL 21744/0001

Marketing Authorisation Holder: Protherics UK Limited, Blaenwaun, Ffostrasol, Llandysul, Ceredigion, SA44 5JT

Job Code: UK-DGF-2400019 | **Date of Preparation:** July 2026

Adverse reactions should be reported. Reporting forms and information can be found at https://yellowcard.mhra.gov.uk/ or search for MHRA Yellow Card in the Google Play or Apple App Store Adverse reactions should also be reported to BTG International Inc via email at safety@serb.com

ABPI Certification
United Kingdom

Title:	DIGIFab UK Prescribing Information August 2024
Format of final material:	Material
Piece Details:	DigiFab Abbreviated SmPC to appear on marketing materials and give out to UK HCPs if requested.
Material Intent:	Promotional
Audience:	HCPs/HCOs
Item code number:	UK-DGF-2400019

ABPI Certification declaration

This is to certify that the medical signatory has examined the final form of this material to which no further changes are to be made, and that in their belief it is ethical, accurate, and in accordance with the requirements of the ABPI Code of Practice both in spirit and letter, as well as with the relevant advertising regulations. In addition, the signatory confirms their belief that the material is not inconsistent with the Marketing Authorization and the Summary of Product Characteristics and is a fair and truthful presentation of the facts about the medicine.

The nominated signatory/appropriately qualified person has examined the final form and confirms their belief that it accurately reflects the content and presentation certified electronically, and complies with the ABPI Code of Practice.

Signatory	Print Name / Date
Medical Signatory	Dolapo Bamiro 27-Jul-2026 14:12:22 GMT+0000