Prescribing Information for DIGIFab® 40 mg/vial digoxin immune Fab, powder for solution for infusion

Presentation: Powder for solution for infusion.

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

Dosage: It is advised to discuss management of patients with digoxin toxicity with the UK National Poisons Information Service at the following contact phone number**: +44 344 892 0111**. The recommended dose is dependent on level of poisoning (acute, chronic etc.), adult/child and weight, amount of digoxin ingested known, and whether digoxin levels are known. Reconstitute prior to administration and infuse intravenously over a 30-minute period. Please refer to the Summary of Product Characteristics (SmPC) for full dosing and administration information, including reversal failure.

Contraindications: Hypersensitivity to active ingredient or excipients.

Precautions and Warnings: Infusion-related reactions or hypersensitivity reactions 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 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). 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. After successful management of poisoning, digoxin has had to be reinstituted in some cases. There are no data on repeated dosing, or use in impaired 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.

Interactions: May interfere with digoxin immunoassay measurements.

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. There are no fertility data.

Side effects: *Common*: 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.

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

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Adverse reactions should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard 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 vigilance@btgsp.com