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

Presentation: Powder for solution for infusion. Each glass vial of DIGIFAB contains 40 mg 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 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: Discuss management of patients with digoxin toxicity with the UK National Poisons Information Service at the following contact phone number: +44 344 892 0111.

Management follows a step-wise decision process, which is dependent on whether the digoxin poisoning is acute, acute-on-chronic, or chronic, whether the patient is an adult or a child >20kg or a child <20kg, and if the amount of digoxin ingested or serum concentration of digoxin is known.
Refer to full information provided in section 4.2 of the DIGIFAB Summary of Product Characteristics before making prescribing decisions.

DIGIFAB should be reconstituted prior to administration according to the instructions provided in section 6.6 of the DIGIFAB Summary of Product Characteristics.

The final solution of reconstituted and diluted DIGIFAB should be infused intravenously over a 30 minute period. Use immediately after reconstitution.

Record the name of the patient and batch number of the product in order to maintain a link between the patient and the batch of the product.

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. Likelihood of an allergic reaction higher in subjects who are allergic to sheep-derived proteins and papain. Patients should have continuous ECG, temperature, BP 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.

Interactions: May interfere with digoxin immunoassay measurements. In the absence of compatibility studies, this medicinal product must not be mixed with other medicinal products.

Pregnancy and lactation: No data in pregnancy. Breast feeding should be discontinued during treatment.

Side effects: C*ommon*: hypo and hyperkalaemia; headache, confusion; nausea, vomiting, diarrhoea, constipation, abdominal distension; worsening of cardiac failure, chest pain, hypotension; orthostatic hypotension; influenza-like illness; renal failure; fatigue; infusion-site phlebitis.

Pack size: 40 mg/vial digoxin immune Fab, Powder for solution for infusion

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 events 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 events should also be reported to BTG International Inc., at vigilance@btgsp.com