Patient Information Leaflet

DigiFab®, 40 mg/vial, Powder for solution for infusion
(referred to as DigiFab® hereafter in this leaflet).
digoxin immune Fab

Read all of this leaflet carefully before you are given this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor.
- If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. See Section 4.

In this leaflet:

1. WHAT DIGIFAB® IS AND WHAT IT IS USED FOR

DigiFab® belongs to a group of medicines known as digitalis antitoxins. It is a preparation of protein fragments derived from antibodies produced in sheep. DigiFab® binds and neutralises digoxin and other digoxin-like substances.

DigiFab® solution is used to treat an overdose of digoxin and other digoxin-like substances, when stopping taking digoxin and other measures are not sufficient.

DigiFab® solution is also used to treat poisoning resulting from other digoxin-like substances, called cardiac glycosides, that can be found in certain plants.

2. WHAT YOU NEED TO KNOW BEFORE YOU ARE GIVEN DIGIFAB®

You should not be given DigiFab® if you are allergic to DigiFab® or to any of the other ingredients of DigiFab® (for other ingredients see section 6 Other information).

Warnings and precautions. Before you are given DigiFab® you should tell your doctor if:

- You are allergic to papaya extracts, to pineapple or to sheep proteins (sheep protein may be found in cheeses and some meats) are allergic to alpha-gal or have been diagnosed with alpha-gal syndrome.
- You are taking digoxin for heart problems. DigiFab® neutralises digoxin and may cause a worsening of your heart condition).
- You have been treated previously with DigiFab®. Repeat use of DigiFab® may be associated with a severe allergic reaction.

If any of the above apply to you then talk to your doctor who will decide what to do.

Children
There is limited information on the use of DigiFab in children.

Taking other medicines and DigiFab®
Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Pregnancy and breast-feeding
There is no information on the use of DigiFab® in pregnant women or women who are breast-feeding. If you are pregnant, likely to become pregnant or are breast-feeding then you must tell your doctor before taking this medicine. Your doctor will have taken this into account before giving DigiFab®.

Driving and using machines
There is no information on whether DigiFab® affects the ability to drive or operate machines. Ask your doctor for advice.

3. HOW DIGIFAB® WILL BE GIVEN

Your doctor or nurse will usually give you DigiFab® by infusion into a vein. The powder in each vial will be dissolved in sterile water and may be further diluted with sterile saline solution.

Dosage used in children and adults
Your doctor will calculate the amount of DigiFab® that you will be given depending on how much digoxin you have in your body. If the amount of digoxin or digoxin-like substance cannot be calculated, you will be treated with a set dose.

The usual initial dose for adults and children over 20 kg may vary between onevial (40 mg DigiFab®) and 5 vials (200 mg DigiFab®) depending on the type of substance responsible for overdose or poisoning. The dose used for small children under 20 kg will usually be less.

Your doctor will record the batch number of the DigiFab® given to you and this information will be kept in your patient file.

You will be monitored with blood tests and continuous heart monitoring during DigiFab® treatment and for at least 24 hours after DigiFab® treatment has been finished.

If you think you have been given too much DigiFab®
The MA holder is not aware of any patients who have suffered DigiFab® overdoses, so no information on overdose is available. However, if you think you have been given too much DigiFab® tell a doctor or nurse or pharmacist immediately.

If you have further questions on the use of this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, DigiFab® can cause side effects, although not everybody gets them.

The following side effects are important and will require immediate action if you experience them. Tell your doctor or nurse immediately if you experience any of the following symptoms (you may need to stop DigiFab®):

- a sudden allergic reaction with shortness of breath, rash, wheezing and drop of blood pressure
- allergic skin reactions such as rash, itchy skin, hives
- fever

The frequencies at which the above reactions occur are not stated.
The following side effects have also been reported:

Common, affecting up to 1 in 10 people:

- Allergic reaction
- Worsening of heart failure causing retention of fluid
- Chest pain
- Low blood pressure
- Changes in blood test results for potassium (this may affect how the heart works or cause tiredness, weakness or pins and needles)
- Severe kidney disease
- Light-headedness on standing
- Inflammation of vein at site of infusion
- Flu-like symptoms
- Headache, feeling confused, feeling tired
- Nausea, vomiting, diarrhoea or constipation, abdominal distension

Symptoms may occur up to 14 days after the infusion.

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any Possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard
By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW DIGIFAB® IS STORED

You will be given DigiFab® in a hospital. The hospital will store the medicine correctly between 2 and 8°C. Not to be stored in a freezer.

After DigiFab® has been made up, it should be used immediately.

DigiFab® must not be used after the expiry date on the vial and outer carton. The hospital pharmacist will check this before he/she dispenses DigiFab®.

All medicines should be kept out of the reach and sight of children.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What DigiFab® contains

- The active substance is digoxin immune Fab.
- The other ingredients are sodium acetate, acetic acid and mannitol.

What DigiFab® looks like and contents of the pack

DigiFab® is supplied as a sterile, off-white powder in a clear glass vial, closed with a rubber stopper and aluminium flip top seal. Each vial contains 40mg digoxin immune Fab protein.

Each pack contains 1 vial.

Marketing Authorisation Holder and Manufacturer

The marketing authorisation holder is Protherics UK Ltd, Blaenwaun, Ceredigion SA44 5JT, UK.

This leaflet was last approved in July 2024.