DigiFab® Powder for Injection

Contains 40 mg Digoxin-specific antibody fragments f(Ab) (Ovine)

Dij-i-fab

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about DIGIFAB Injection. It does not contain all the available information. It does not take the place of talking to your doctor.

All medicines have risks and benefits. Your doctor has weighed the risks of you being given DIGIFAB Injection against the benefits they expect it will have for you.

If you have any concerns about being given this medicine, ask your doctor.

Keep this leaflet in a safe place.

You may need to read it again.

What DIGIFAB Injection is used for

DIGIFAB Injection is an antidote used to treat life-threatening digoxin overdose.

DIGIFAB Injection belongs to a group of medicines called the antigen binding fragments.

DIGIFAB is a sterile freeze-dried powder of antigen binding fragments (Fab) obtained from antidigoxin antibodies raised in sheep.

Fab fragments react with digoxin in the blood to prevent death from digoxin overdose.

The total number of people treated with this medication in trials is small and the data regarding dosing and outcomes are limited.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

This medicine is available only with a doctor's prescription.

Before you are given DIGIFAB Injection

When you must not be given it

You should not be given DIGIFAB Injection if you have an allergy to:

- Any medicine containing digoxin-specific Fab fragments
- Any of the ingredients listed at the end of this leaflet.
- Papain, chymopapain, or other papaya extracts
- Alpha-gal or have been diagnosed with alpha-gal syndrome
- Any other similar medicines.

Some of the symptoms of an allergic reaction may include:

- Shortness of breath
- Wheezing or difficulty breathing
- Swelling of the face, lips, tongue or other parts of the body
- Rash, itching or hives on the skin.

If you are not sure whether you should be given this medicine, talk to your doctor.

Before you are given it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes, including any allergy to sheep protein and pineapple enzyme bromelain and alpha-gal.

Tell your doctor if you have or have had any of the following medical conditions:

- Previously received treatment with a similar medication made from Fab fragments
- Kidney disease.

Tell your doctor if you are pregnant, plan to become pregnant or are breast-feeding.
Your doctor can discuss with you the risks and benefits involved.

If you have not told your doctor about any of the above, tell him/her before you are given DIGIFAB Injection.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket, health food shop, naturopath or herbalist.

Some medicines may be affected by DIGIFAB Injection or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor has more information on medicines to be careful with or avoid while being given this medicine.

How DIGIFAB Injection is given

DIGIFAB Injection must only be given by a doctor or nurse.

How it is given

DIGIFAB Injection is initially dissolved in sterile water for injections before being further diluted in 0.9% saline and slowly injected into a vein over a period of 30 minutes.

When initially reconstituted in water for injections the resulting solution may be clear to slightly opalescent and colourless to pale yellow. However, once DIGIFAB is further diluted for use in 0.9% saline, the solution is normally a clear, colourless solution.

The doctor or nurse will check to ensure the medicine is not past its expiry date and has not been tampered with.

How much is given

Your doctor will decide what dose of DIGIFAB you will receive and how long you will receive it for. This depends on your medical condition and other factors, such as your weight.

If you are given too much (overdose)

As DIGIFAB Injection is always given to you in a hospital under the supervision of a doctor, it is unlikely that you will receive an overdose.

Symptoms of an overdose are the same as side effects but may be more severe. The symptoms of a side effect are listed under **Side effects** below.

If you notice any symptoms of an overdose immediately contact your doctor or go to the Emergency Department at the nearest hospital.

Contact the Poisons information centre on 13 11 26 for further advice on overdose management.

While you are being given DIGIFAB Injection

Things you must do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you have been given DIGIFAB Injection.

Tell any other doctors, dentists, and pharmacists who treat you that you have been given this medicine.

If you are going to have surgery, tell the surgeon or anaesthetist that you have been given this medicine.
It may affect other medicines used during surgery.

If you become pregnant while being given this medicine, tell your doctor immediately.

If you are breastfeeding or planning to breast feed, tell your doctor immediately.

If you are about to have any blood tests, tell your doctor that you are being given this medicine.
It may interfere with the results of some tests, for example digoxin blood levels.

Keep all of your doctor's appointments so that your progress can be checked.

Things to be careful of

DIGIFAB Injection can lower the potassium levels in your blood. For this reason, the potassium levels in your blood should be closely monitored, particularly in the first few hours after DIGIFAB Injection has been given.

Side effects

Check with your doctor as soon as possible if you think you are experiencing any side effects or an allergic reaction after receiving DIGIFAB Injection, even if the problem is not listed below.

Due to limited data being available on the medicine, reporting of any concerns or side effects to the drug company or the Therapeutic Goods Administration (TGA) is encouraged.

Your doctor or pharmacist can report the side effects on your behalf or help you with the report.

Like other medicines, DIGIFAB Injection can cause some side effects. If they occur, they are most likely to be minor and temporary. However, some may be serious and need medical attention.

Side effects can occur up to 14 days after the medicine has been given.

The most commonly reported side effect is low or high potassium concentration.

Tell your doctor if you notice any of the following:

- headache
- nausea and vomiting
- fatigue
- irritation at the infusion site

In some cases, poor heart function may be worsened because the effects of digoxin have been neutralised.

Rarely, allergic reactions (e.g. swelling at injection site, swelling of the face, rash) have occurred.

Tell your doctor or nurse in the hospital immediately if you notice any of the following:

- **Wheezing,**
- **Swelling of the lips/mouth,**
- **Difficulty in breathing,**
- **Hayfever,**
- **Lumpy rash (hives)**
- **Fainting.**

These could be symptoms of an allergic reaction. These are serious side effects. You may need urgent medical attention.

This is not a complete list of all possible side effects. Others may occur in some people and there may be some side effects not yet known.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

After being given DIGIFAB Injection

Storage

DIGIFAB Injection will be stored in the surgery, pharmacy or ward of a hospital. The injection is kept in refrigerator, where the temperature stays between 2-8°C.

DIGIFAB Injection will only be opened when it is time for you to have the injection.

Product description

What it looks like

DIGIFAB Injection is an off-white powder in clear glass vial sealed with a butyl rubber stopper and aluminium flip top seal.

The vial stopper is not made with natural rubber latex.

Ingredients

DIGIFAB Injection contains 40 mg of Digoxin-specific Fab.

It also contains:

- 75 mg mannitol and
- 1.7 mg sodium acetate

This medicine does not contain lactose, sucrose, gluten, tartrazine, alcohol, dyes or preservatives.

Supplier

DIGIFAB Injection is supplied in Australia by:

Phebra Pty Ltd
19 Orion Road,
Lane Cove West,
NSW 2066, Australia.
Telephone: 1800 720 020

DIGIFAB Injection is manufactured by:

BTG International Inc.
West Conshohocken, PA 19428
USA

Australian Registration Number

DIGIFAB 40 mg powder for injection - AUST R 203623

Date of preparation

November 2022