

DIGIFab[®]

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I being given DIGIFab?

DIGIFab Injection contains the active ingredient Digoxin-specific antibody fragment f(Ab) (Ovine). DIGIFab is an antidote used to treat life-threatening digoxin overdose.

For more information, see Section [1. Why am I being given DIGIFab?](#) in the full CMI.

2. What should I know before DIGIFab is given?

Do not use if you have ever had an allergic reaction to DIGIFab or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before DIGIFab Injection is given?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with DIGIFab Injection and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How is DIGIFab given?

- DIGIFab Injection must only be given by a doctor or nurse.
- 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.

More instructions can be found in Section [4. How is DIGIFab given?](#) in the full CMI.

5. What should I know while DIGIFab is being given?

<p>Things you should do</p>	<ul style="list-style-type: none"> • Remind any doctor, dentist or pharmacist you visit that DIGIFab is being given. • Tell your surgeon or anaesthetist before surgery that you have been given this medicine. • Tell your doctor if you are about to start on any new medicine that you are being given DIGIFab injection. • Tell your doctor immediately, if you become pregnant while being given this medicine. • Tell your doctor immediately, if you are breastfeeding or planning to breast feed. • 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 levels
<p>Looking after your medicine</p>	<ul style="list-style-type: none"> • 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.

For more information, see Section [5. What should I know while DIGIFab is being given?](#) in the full CMI.

6. Are there any side effects?

Common side effects include low or high potassium concentration, headache, nausea and vomiting, fatigue, irritation at the infusion site, worsening of poor heart function due to the neutralised effects of digoxin, swelling at injection site, swelling of the face. Serious side effects include wheezing, swelling of the lips/mouth, difficulty in breathing, hayfever, lumpy rash (hives) and fainting. For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

DIGIFab[®] (Dij-i-fab)

Active ingredient: *Digoxin-specific antibody fragment f(Ab) (Ovine)*

Consumer Medicine Information (CMI)

This leaflet provides important information about using DIGIFab. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using DIGIFab.**

Where to find information in this leaflet:

1. [Why am I being given DIGIFab?](#)
2. [What should I know before DIGIFab is given?](#)
3. [What if I am taking other medicines?](#)
4. [How is DIGIFab given?](#)
5. [What should I know while DIGIFab is being given?](#)
6. [Are there any side effects?](#)
7. [Product details](#)

1. Why am I being given DIGIFab?

DIGIFab Injection contains the active ingredient Digoxin-specific antibody fragment f(Ab) (Ovine). 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.

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

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.

2. What should I know before DIGIFab is given?

Warnings

You should not be given DIGIFab if you are allergic to:

- any medicine containing digoxin-specific Fab fragments or 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.

Always check the ingredients to make sure you can use this medicine.

Some of the symptoms of 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.

Check with 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.
- have or have had any of the following medical conditions:
 - previously received treatment with a similar medication made from Fab fragments
 - kidney disease.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

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.

3. What if I am taking other medicines?

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

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.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect DIGIFab.

4. How is DIGIFab given?

How much DIGIFab 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.

How is DIGIFab given

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

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.

If too much DIGIFab is given

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 think you have used too much DIGIFab, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling **13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while DIGIFab is being given?

Things you should 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, dentist and pharmacist 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 these medicines, 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 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.

Looking after your medicine

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.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none"> • low or high potassium concentration • headache • nausea and vomiting • fatigue • irritation at the infusion site 	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

<ul style="list-style-type: none"> worsening of poor heart function due to the neutralized effects of digoxin swelling at injection site swelling of the face rash 	
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Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> wheezing, swelling of the lips/mouth difficulty in breathing hayfever lumpy rash (hives) fainting 	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

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

What DIGIFab contains

Active ingredient	Digoxin-specific Fab: 40 mg
Excipients	mannitol: 75 mg sodium acetate: 1.7 mg

Do not take this medicine if you are allergic to any of these ingredients.

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

What DIGIFab 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.

DIGIFab 40 mg powder for injection is available as one vial per carton (AUST R 203623).

Who distributes DIGIFab

Phebra Pty Ltd
17-19 Orion Road
Lane Cove West, NSW 2066
Australia
Telephone: 1800 720 020

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