

Kit for preparation of Technetium (99mTc) sestamibi injection

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.

This medicine is new or being used differently. Please report side effects. See the [full CMI](#) for further details.

1. Why am I using [medicine name]?

CARDIOLITE® contains the active ingredient tetrakis(2-methoxyisobutylisonitrile) copper(1) tetrafluoroborate. CARDIOLITE® is used show the blood flow inside your heart during exercise and rest and the presence and size of any breast cancer.

For more information, see Section [1. Why am I using \[medicine name\]?](#) in the full CMI.

2. What should I know before I use CARDIOLITE®?

Do not use if you have ever had an allergic reaction to CARDIOLITE® 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, are pregnant or plan to become pregnant and are breastfeeding or plan to breastfeed.

For more information, see Section [2. What should I know before I use \[medicine name\]?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with CARDIOLITE® 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 do I use CARDIOLITE®?

- Your doctor will decide how much you will be given. This depends on your condition and other factors, such as weight.
- CARDIOLITE® is given as an injection into a vein.

More instructions can be found in Section [4. How do I use \[medicine name\]?](#) in the full CMI.

5. What should I know while using CARDIOLITE®?

Things you should do	<ul style="list-style-type: none">• Remind any doctor you visit that you are allergic Cardiolite or any of the ingredients listed at the end of this leaflet.• Tell your doctor if you have heart disease.• Tell your doctor as soon as possible if you do not feel well during the injection or after being given CARDIOLITE® and if you experience any side effects during or after the CARDIOLITE® administration.• drink about 2 litres of fluid and void urine frequently immediately after the procedure.
Things you should not do	<ul style="list-style-type: none">• taking any other medicines until advised by your doctor
Driving or using machines	<ul style="list-style-type: none">• Do not drive or operate machinery until you know how CARDIOLITE® affects you.

For more information, see Section [5. What should I know while using \[insert medicine\]?](#) in the full CMI.

6. Are there any side effects?

Common side effects that are usually mild: headache, nausea, difference in taste, sleep disorders, breast pain (for women who had breast imaging), transient arthritis, flushing, oedema, injection site inflammation, dry mouth and fatigue.

Serious side effects could be chest pain or a feeling of tightness, pressure or heaviness in the chest; swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing; changes in your heart rate; feeling faint; vomiting; rash, itching, hives; allergic reaction (shortness of breath or difficulty breathing, slow heart rate, dizziness or light-headedness, feeling unusually tired or weak) and fever. 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.

Kit for preparation of Technetium (99mTc) sestamibi injection

Active ingredient(s): *tetrakis(2-methoxyisobutylisonitrile) copper(1) tetrafluoroborate*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Cardiolite®. 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 Cardiolite®.

Where to find information in this leaflet:

- [1. Why am I using \[medicine name\]?](#)
- [2. What should I know before I use \[medicine name\]?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use \[medicine name\]?](#)
- [5. What should I know while using \[medicine name\]?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using CARDIOLITE®?

Cardiolite® contains the active ingredient *tetrakis(2-methoxyisobutylisonitrile) copper(1) tetrafluoroborate*. Cardiolite® is a prescription medicine which is only available to the Healthcare Practitioners for diagnostic use only. It belongs to a group of medicines called radiopharmaceutical agents, which are all radioactive. It is administered to you via intravenous injection after mixing with a radioactive solution.

Cardiolite® is used to show:

- The blood flow inside your heart during exercise and rest.
- The presence and size of any breast cancer.

Your doctor may have prescribed Cardiolite® for another purpose. Ask your doctor if you have any questions about why Cardiolite® has been prescribed for you. If you have any concerns, you should discuss these with your doctor.

2. What should I know before I use CARDIOLITE®?

Warnings

Do not use Cardiolite® if:

- You are **allergic to** any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.
- **You are below 18 years old.** However, If your doctor believes it is necessary to give Cardiolite to you 18, he or she will discuss the benefits and risks with you.

Check with your doctor if you:

- Have any other medical conditions, especially if you have been told that you have or suspected of having a cardiac (heart) disease.
- Have allergies to ingredients listed at the end of this leaflet or any other substances such as foods, preservatives or dyes.
- Take any medicines for any other condition, including medicines that you buy without prescription from pharmacy, supermarket or health food shop.

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

Tell your doctor if you are pregnant or intend to become pregnant.

Like most medicines Cardiolite® is not recommended for use during pregnancy. If there is a need to consider Cardiolite® during your pregnancy, your doctor will discuss the benefits and risks of giving it to you.

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

Like most medicines Cardiolite® is not recommended while you are breastfeeding. However if you are breastfeeding, formula feedings should be substituted for breastfeeding for 24 hours following the administration of Cardiolite®. Breast milk produced within that time should be discarded.

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.

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

4. How do I use CARDIOLITE®?

How much to take / use

- Your doctor will decide how much you will be given CARDIOLITE®. This depends on your condition and other factors, such as weight.
- If you are being given CARDIOLITE® for heart imaging you may be given two injections, one at rest and one with exercise. You may be asked to fast for 4 hours before the procedure, and may be given a light meal after the injection.
- If you are being given CARDIOLITE® for breast imaging you will be given one injection.
- CARDIOLITE® will only be given to you by a doctor or a nurse.

When to take / use CARDIOLITE®

- Cardiolite may cause dizziness some people. Make sure you know how you react to Cardiolite before you drive a car, operate machinery or do anything else that could be dangerous if you are dizzy.

Do not drive or operate machinery until you know how Cardiolite affects you.

If you take too much CARDIOLITE®

If you think that you have been injected with too much CARDIOLITE®, drink plenty of water or fluid for frequent urination. This will remove as much radioactivity as possible from your bladder.

If you experience immediate side effects, 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 using CARDIOLITE®?

Things you should do

Tell your doctor as soon as possible if you do not feel well during the injection or after being given CARDIOLITE®.

All medicines have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some side effects.

Tell your doctor or nurse if you experience any of the following and they worry you

- headache
- flushing
- nausea
- altered taste
- pain/inflammation at the injection site
- sleep disorders (such as nightmares, sleep terror or sleepwalking)
- breast pain (for women who had breast imaging)
- transient arthritis
- oedema
- dry mouth
- fatigue

These are usually mild and resolve within 15 minutes.

You must drink about 2 litres of fluid and void urine frequently immediately after the procedure. This will remove as much radioactivity as possible from your bladder.

Things you should not do

Do not take any other medicines until advised by your doctor.

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">• headache• nausea• things taste different• sleep disorders• breast pain• transient arthritis• flushing• oedema• injection site inflammation• dry mouth• fatigue	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none">• chest pain or a feeling of tightness, pressure or heaviness in the chest• changes in your heart rate• swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing• feeling faint• vomiting• abdominal pain• rash, itching or hives (itchy swellings on the skin)• allergic reaction – shortness of breath or difficulty breathing, slow heart rate, dizziness or light-headedness, feeling unusually tired or weak• fever	<p>Call your doctor or nurse straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

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

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.

7. Product details

This medicine is only with a doctor's prescription and only made available to your doctor only.

What CARDIOLITE® contains

Active ingredient (main ingredient)	tetrakis (2methylisobutylisonitrile) copper (1) tetrafluoroborate
Other ingredients (inactive ingredients)	<p>Before reconstitution:</p> <ul style="list-style-type: none">• tetrakis (2-methylisobutylisonitrile) copper (1) tetrafluoroborate• stannous chloride• sodium citrate• cysteine hydrochloride• mannitol <p>After reconstitution:</p> <ul style="list-style-type: none">• Sodium Pertechnetate (99mTc)• water for injection.

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

What CARDIOLITE® looks like

CARDIOLITE® is supplied in vials. An injection is prepared from the vial immediately before it is injected.
(AUST R 49688).

Who distributes [medicine name]

Global Medical Solutions Australia Pty Limited T/A Radpharm Scientific

53-57 Oatley Court, BELCONNEN, ACT 2617 Australia

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