CARDIOLITE®

Technetium Tc-99m Sestamibi

Consumer Medicine Information

What is in this leaflet

This leaflet answers some of the common questions about Cardiolite. It does not contain all of the available information about Cardiolite. It does not replace talking to your doctor.

All medicines have risks and benefits. Your doctor has weighed the risks of you or your child receiving Cardiolite against the benefits he or she expects it will have.

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

Keep this leaflet.

You may need to read it again.

What is Cardiolite

Cardiolite contains the active ingredient called Technetium Tc-99m Sestamibi and belongs to a group of medicines called radiopharmaceutical agents, which are all radioactive.

Cardiolite comes in a kit, containing ingredients that are mixed with a radioactive solution before being given to you as an injection.

What Cardiolite is used for

Cardiolite is used to show the blood flow inside your heart during exercise and rest. Cardiolite can be used to show 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.

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

Before you are given Cardiolite

Before you are given Cardiolite your doctor will explain to you the procedure you are about to undergo, and the radioactive medicine you will be given. You must discuss any concerns you have with your doctor.

Cardiolite is not recommended for patients less than 18 years of age. If your doctor believes it is necessary to give Cardiolite to a patient under 18, he or she will discuss the benefits and risks with you.

You must tell your doctor if you have allergies to:

- any other medicines
- any other substances such as foods, preservatives or dyes

Tell your doctor if you are or plan 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.

Tell your doctor if you are breastfeeding or plan 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.

Tell your doctor if you have any other medical conditions,

especially if you suffer from heart disease.

Taking other medicines

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

How Cardiolite is given

How much is given

Your doctor will decide how much you will be given. 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.

How it is given

Cardiolite is given as an injection into a vein. Cardiolite should only be given by a doctor or a nurse.

When you are given Cardiolite

Things you must do

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 must not do

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

Things to be careful of

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

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.

Side effects

Tell your doctor as soon as possible if you do not feel well 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 if you experience any of the following and they worry you:

- headache
- nausea
- things taste different
- sleep disorders (such as nightmares, sleep terror or sleepwalking)
- breast pain (women having breast imaging)
- · transient arthritis
- flushing
- oedema
- injection site inflammation
- dry mouth
- fatigue

These side effects are usually mild.

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

- 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
- abdominal pain
- rash, itching or hives (itchy swellings on the skin)
- allergic reaction shortness of breath or difficulty breathing, slow heart rate, dizziness or lightheadedness, feeling unusually tired or weak
- fever

These are serious side effects for which you may need urgent medical treatment.

Do not be alarmed by this list of side effects.

You may not experience any of them.

Product description

What it looks like

Cardiolite is supplied in vials. An injection is prepared from the vial immediately before it is injected.

Ingredients

Active ingredient:

Technetium Tc-99m Sestamibi.

Ingredients before reconstitution:

- tetrakis (2methylisobutylisonitrile) copper (1) tetrafluoroborate,
- stannous chloride,
- sodium citrate,
- cysteine hydrochloride, and
- mannitol.

Sodium pertechnetate Tc-99 in water for injections.

Sponsor

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Registration Number

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Date of Preparation

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