

Package leaflet: Information for the user

Cardiogen-82 3.3–5.6 GBq radionuclide generator

Strontium-82 (Sr-82) chloride/Rubidium-82 (Rb-82) chloride

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 or your nuclear medicine specialist who will supervise the procedure.
- If you get any side effects, talk to your doctor or your nuclear medicine specialist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Cardiogen-82 is and what it is used for
2. What you need to know before Cardiogen-82 is used
3. How Cardiogen-82 is used
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1. What Cardiogen-82 is and what it is used for

This medicinal product is a radiopharmaceutical product for diagnostic use only.

Cardiogen-82 is a strontium-82 (Sr-82) chloride/rubidium-82 (Rb-82) chloride radionuclide generator used to produce an injectable solution of rubidium-82 (Rb-82) chloride.

The obtained solution of rubidium-82 (Rb-82) chloride is used in Positron Emission Tomography (PET) imaging examinations in order to study heart function and blood flow (myocardial perfusion) in adults with suspected or known coronary artery disease.

The use of Cardiogen-82 does involve exposure to small amounts of radioactivity. Your doctor and the nuclear medicine specialist have considered that the clinical benefit that you will obtain from the procedure with the radiopharmaceutical outweighs the risk due to radiation.

2. What you need to know before Cardiogen-82 is used

Cardiogen-82 must not be used:

- if you are pregnant,
- if the amount of strontium-82 and/or strontium-85 is too high,
- with solutions other than the additive-free Sodium Chloride Infusion (0.9% w/v).

Warnings and precautions

Talk to your nuclear medicine specialist in the following cases:

- if you have heart failure,
- if you are pregnant or think you may be pregnant,
- if you are breast-feeding,

Cardiogen-82 radionuclide generator

- if you are under 18 years of age,
- if you suffer from allergies.

Children and adolescents

Talk to your nuclear medicine specialist if you are under 18 years old.

Before administration of Cardiogen-82 you should:

- be fasting for at least 6 hours,
- avoid caffeine intake for at least 12 hours.

Tell your healthcare professional if you have recently had a heavy meal, or if you have consumed food or beverages that contain caffeine, such as coffee, tea, soft drinks, chocolate, etc.

Other medicines and Cardiogen-82

Tell your nuclear medicine specialist if you are taking, have recently taken or might take any other medicines, since these may interfere with the interpretation of the images.

- asthma medication,
- heart medication,
- blood pressure medication,
- blood thinners (anticoagulants),
- medicines which reduce the production of acid by the stomach (proton pump inhibitors (PPIs)).

Pregnancy and breast-feeding

If you are pregnant, or if you think you may be pregnant (e.g., you have missed your period) or if you are planning to have a baby, ask your nuclear medicine specialist for advice before you are given this product.

The use of Cardiogen-82 is contraindicated during pregnancy.

When in doubt, it is important to consult your nuclear medicine doctor who will supervise the procedure.

If you are breast-feeding, please talk to your nuclear medicine specialist who may advise you to stop breast-feeding until the radioactivity has left your body. This will happen by about one hour after the last administration of this medicine. Please ask your nuclear medicine specialist when you can resume breast-feeding.

Driving and using machines

It is considered unlikely that Cardiogen-82 will affect your ability to drive or to use machines.

Cardiogen-82 contains sodium

This medicine contains sodium. This medicine may contain more than 1 mmol (23 mg) of sodium per administered dose. This should be taken into account in patients who are controlling their intake of dietary sodium.

3. How Cardiogen-82 is used

There are strict laws on the use, handling and disposal of radiopharmaceutical products. Cardiogen-82 will only be used in special controlled areas. This product will only be handled and given to you by people who are qualified and trained to use it safely. These people will take special care for the safe use of this product and will keep you informed of their actions.

The nuclear medicine specialist supervising the procedure will decide on the quantity of Cardiogen-82 to be used in your case. It will be the smallest quantity necessary to get the desired information.

The quantity to be administered usually recommended for an adult ranges from 1110 to 2220 MBq. Megabecquerel (MBq) is the unit used to express the amount of radioactivity.

Administration of Cardiogen-82 and conduct of the procedure

Cardiogen-82 is administered into a vein (intravenous administration). In general, two injections are necessary, one at rest and one under pharmacological stress. The two injections will be done at least 10 minutes apart and the scanning will take place within 5 minutes each time.

The nuclear medicine doctor will inform you if you need to take any special precautions after receiving this medicine. Contact your nuclear medicine doctor if you have any questions.

Duration of the procedure

Your nuclear medicine specialist will inform you of the usual duration of the procedure.

As a general rule, the procedure should not last more than 1-2 hours in total.

After administration of Cardiogen-82:

The nuclear medicine specialist will inform you if you need to take any special precautions after receiving this medicine. Contact your nuclear medicine specialist if you have any questions.

If you have been given more Cardiogen-82 than you should

An overdose is unlikely because you will only receive two single doses that are each precisely controlled by the nuclear medicine specialist supervising the procedure. However, in the case of an overdose, your nuclear medicine specialist will consult with you regarding appropriate next steps.

Should you have any further questions on the use of this medicine, please ask the nuclear medicine specialist who supervises the procedure.

4. Possible side effects

No side effects have been reported due to Cardiogen-82.

This radiopharmaceutical product will deliver low amounts of ionising radiation, which is associated with very low risk of cancer and hereditary abnormalities (passing on faulty genes).

Your doctor has considered that the clinical benefit that you will obtain from the procedure with the radiopharmaceutical outweighs the potential risk due to radiation.

You may experience side effects from the administration of the medicine that produces pharmacologic stress (a medicine that shows how well blood flows to the muscles of the heart).

If you experience any side effect, please refer immediately to your nuclear medicine specialist. This includes any possible side effects not listed in this leaflet.

Reporting of side effects

If you get any side effects, talk to your nuclear medicine specialist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system: Yellow Card Scheme at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side effects, you can help provide more information on the safety of this medicine.

5. How Cardiogen-82 is stored

You will not have to store this medicine. This medicine is stored under the responsibility of the specialist in appropriate premises. Storage of radiopharmaceuticals will be in accordance with current national regulation on radioactive materials.

Store below 25°C.

The following information is intended for the specialist only.

This product must not be used after the expiry date which is stated on the label (after {DD MM YYYY hh:mm UTC}).

6. Contents of the pack and other information

What Cardiogen-82 contains

- The active substances are:
Strontium (Sr-82) chloride (parent nuclide) and rubidium (Rb-82) chloride (daughter nuclide)
- At the date of calibration, the radionuclide generator contains:
Strontium (Sr-82) chloride/Rubidium (Rb-82) chloride: 3.3 to 5.6 GBq
- The other ingredients are:
Solution for elution: sodium chloride 0.9% w/v

What Cardiogen-82 looks like and contents of the pack

Cardiogen-82 is a radionuclide generator housed in a labelled, lead-lined plastic container.

You will not have to obtain or handle this medicine.

Marketing Authorisation Holder

Bracco UK Limited
Magdalen Centre,
The Oxford Science Park

Cardiogen-82 radionuclide generator

1 Robertson Avenue,
Oxford OX4 4GA
United Kingdom

Manufacturer

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Magdalen Centre,
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1 Robertson Avenue,
Oxford OX4 4GA
United Kingdom

This leaflet was last revised in month January 2023.

The following information is intended for healthcare professionals only:

The Summary of Product Characteristics (SmPC) of Cardiogen-82 is available at <https://products.mhra.gov.uk/>, with the objective to provide healthcare professionals with other additional scientific and practical information about the administration and use of this radiopharmaceutical product.

Please refer to the SmPC.