1. What Thallium (\(^{201}\text{Tl}\)) chloride injection is and what it is used for
This medicine is a radiopharmaceutical product for diagnostic use only.

When injected into a vein of your arm, thallium (\(^{201}\text{Tl}\)) chloride, the radioactive element, temporarily collects in a specific part of your body like heart, muscles, parathyroid glands, brain or thyroid. Because of its radioactivity, it can be easily detected from outside your body using a special camera, and pictures, known as scans, can be taken. These scans give valuable information on either the structure of the organ or how efficiently processes associated with blood flow through the organ are being carried out.

In particular, the thallium (\(^{201}\text{Tl}\)) chloride can be used:

- to examine the heart, the leg muscles and the parathyroid gland, or
- to show up brain and thyroid tumours.

Your doctor / nuclear medicine specialist will explain to you what kind of examination will be performed.

The use of Thallium (\(^{201}\text{Tl}\)) chloride does involve exposure to amounts of radioactivity. Your doctor and the nuclear medicine doctor 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 thallium (\(^{201}\)Tl) chloride is used**

 **Thallium (\(^{201}\)Tl) chloride** must not be used:
- If you are **allergic** to thallium (\(^{201}\)Tl) chloride or any of the other ingredients of this medicine (listed in section 6).
- If you are **pregnant** or or believe you may be pregnant **If you are breast-feeding**
- If you are under 18 years old.

**Warnings and precautions**
Some examinations of heart behaviour involve exercising to make the heart work harder. Your doctor / nuclear medicine doctor will only consider this type of test if she/he is certain that the exercise will not be harmful to you.

**Before administration of Thallium (\(^{201}\)Tl) chloride you should:**
- **be fasting for at least 4 hours.**
- **drink plenty of water** before the start of the examination in order to urinate as often as possible during the first hours after the study.

**Children and adolescents**
Talk to your nuclear medicine doctor if you are under 18 years old.

**Other medicines and Thallium (\(^{201}\)Tl) chloride injection**

Tell your **nuclear medicine doctor** if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription since they may interfere with the interpretation of the images. Particular examples are:
- Medicines used **to treat heart conditions and high blood pressure** (dipyridamole, adenosine, isoprenaline, dobutamine, nitrates, beta-blockers, digitalis analogues,…)
- **insulin** (medicine used to treat Diabetes Mellitus),
- Medicines used **to treat breathing difficulty** (methylxanthines (i.e. theophyllin))

**Pregnancy and breast-feeding**
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your nuclear medicine doctor for advice before you are given this medicine.

You must inform the nuclear medicine doctor before the administration of **Thallium (\(^{201}\)Tl) chloride** if there is a possibility you might be pregnant, if you have missed your period or if you are breast-feeding. When in doubt, it is important to consult your nuclear medicine doctor who will supervise the procedure.

If you are pregnant
**You must not be given Thallium (\(^{201}\)Tl) chloride if you are pregnant.** It must be established that you are not pregnant before the use of this product.
**So you must tell your doctor/nuclear medicine specialist** if you have missed a period or if there is any chance you may be pregnant. Investigations in nuclear medicine may involve a risk to the unborn.

If you are breast-feeding
**Tell your nuclear medicine doctor if you are breast-feeding,** as you should completely stop this before treatment.
Moreover you may need to **avoid close contact** with your baby for a while depending on the dose administered. Your nuclear medicine doctor will inform you. Please ask your nuclear medicine doctor when you can resume breast-feeding.
Driving and using machines

It is considered unlikely that Thallium\(^{201}\text{Tl}\) chloride will affect your ability to drive or to use machines.

Thallium\(^{201}\text{Tl}\) chloride contains less than 1 mmol of sodium (23 mg) per vial, i.e. essentially ‘sodium-free’

3. How thallium\(^{201}\text{Tl}\) chloride is used

There are strict laws on the use, handling and disposal of radiopharmaceutical products. Thallium\(^{201}\text{Tl}\) chloride will only be used in special controlled areas. This product will only be handled and given to you by people who are trained and qualified to use it safely. These persons will take special care for the safe use of this product and will keep you informed of their actions.

The nuclear medicine doctor supervising the procedure will decide on the quantity of Thallium\(^{201}\text{Tl}\) chloride 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 is about 1 MBq per kg (MBq: megabecquerel, the unit used to express radioactivity).

Administration of Thallium\(^{201}\text{Tl}\) chloride and conduct of the procedure

Thallium\(^{201}\text{Tl}\) chloride will be injected into a vein of your arm.

Usually one injection is sufficient to provide your doctor with the information needed although sometimes a second injection may be required.

The injection may be given either at rest or during the course of a stress test in which either exercise or the administration of another medicinal product is used to make your heart work harder.

Scans may be taken at any time from the beginning of the injection, depending on which images are required. Additional scans, possibly involving a second injection may be performed between 3 and 24 hours after the first injection.

Duration of the procedure

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

After administration of Thallium\(^{201}\text{Tl}\) chloride, you should urinate frequently in order to eliminate the product from your body.

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.

If you have been given more Thallium\(^{201}\text{Tl}\) chloride than you should

An overdose is unlikely, since Thallium\(^{201}\text{Tl}\) chloride is administered by a doctor under strictly controlled conditions. However, in the case of an overdose, you will receive the appropriate treatment. You will be asked to drink plenty of water and to take laxatives to increase the elimination of the product from your body.

Should you have any further question on the use of Thallium\(^{201}\text{Tl}\) chloride, please ask the nuclear medicine doctor who supervises the procedure.
4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Possible side effects

**Rare** (frequency lower than one out of 1,000 patients and higher than one out of 10,000 patients)
- Allergy (rash, itching)
- Fainting (Vasovagal syncope).

**Frequency not known:**
- Local skin damage (necrosis) has been reported when the injection was not in the vein.
- Any radioactive material may cause cancer or hereditary defects, but the frequency of these adverse reactions is not known.

Reporting of side effects

*If you get any side effects*, talk to your nuclear medicine doctor. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme. Website: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard).

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

5. How thallium (\(^{201}\)Tl) chloride 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 national regulation on radioactive materials.

6. Contents of the pack and other further information

**What Thallium (\(^{201}\)Tl) chloride injection contains**
- The active substance is Thallium (\(^{201}\)Tl) chloride.
- The other ingredients are sodium chloride, nitric acid and water for injections.

**What Thallium (\(^{201}\)Tl) chloride injection looks like and contents of the pack**

You will not have to get or to manipulate this medicine, what follows is only for your information.

*Thallium (\(^{201}\)Tl) chloride* is a sterile, clear and colourless solution for injection.

Packsize: A multidose vial can contain from 1 to 10 ml of solution for injection, corresponding to 37 up to 370 MBq per vial at calibration date.

**Marketing Authorisation Holder and Manufacturer**

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Detailed information on this medicine is available on the web site of the MHRA.

The following information is intended for medical or healthcare professionals only:

The complete SmPC of Thallium (\textsuperscript{201}TI) chloride is provided as a separate document in the product package, with the objective to provide healthcare professionals with other additional scientific and practical information about the administration and use of this radiopharmaceutical.

Please refer to the SmPC.