

Thallous (Tl201) Chloride Injection**37 MBq/ml solution for injection**

Thallous (Tl-201) 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 nuclear medicine doctor who will supervise the procedure.
- If you get any side effects, talk to your nuclear medicine doctor. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Thallous (Tl201) Chloride is and what it is used for
2. What you need to know before Thallous (Tl201) Chloride is used
3. How Thallous (Tl201) Chloride is used
4. Possible side effects
5. How Thallous (Tl201) Chloride is stored
6. Contents of the pack and other information

1. What Thallous (Tl201) Chloride is and what it is used for

This medicine is a radiopharmaceutical product for diagnostic use only.

This medicine contains thallous (Tl-201) chloride, a radioactive substance which when injected, collects in certain organs, such as the heart.

The radioactive substance can be photographed from outside the body, using special cameras which take a scan. This scan shows where the radioactivity is inside the organ and the body. This gives the doctor valuable information about how that organ is working.

Thallous (Tl201) Chloride is used to make a scan of the:

- heart muscle and blood circulation in the heart, to examine heart diseases
- leg muscles, to examine the blood flow in the muscles in a certain condition where the arteries in the limbs are narrowed (peripheral vascular disorder)
- parathyroid gland
- certain tumours known to take up thallium, such as brain or thyroid tumours and metastases.

The use of Thallous (Tl201) Chloride does involve exposure to small 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 Thallous (Tl201) Chloride is used

Thallous (Tl201) Chloride must not be used

if you are

- allergic to thallous chloride or any of the other ingredients of this medicine (listed in section 6)
- pregnant
- breastfeeding
- under 18 years old

Warnings and precautions

Talk to your nuclear medicine doctor before you are given Thallous (Tl201) chloride, if you have a reduced kidney or liver function.

Before administration of Thallous (Tl201) Chloride you should

- 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.
- be fasting for at least 4 hours.

Children and adolescents

Thallous (Tl201) chloride should not be used in children below the age of 18 years.

Other medicines and Thallous (Tl201) Chloride

Tell your nuclear medicine doctor if you are taking or have recently taken any other medicines since they may interfere with the examination or the interpretation of the images. The nuclear medicine doctor will tell you if you need to stop taking certain medicines before the procedure, and for how long.

Examples are:

- certain products containing **methylxanthines** such as certain medicines to treat migraine, and **theophylline** (a medicine to treat asthma and other breathing diseases)
- **dipyridamole**: a medicine to reduce blood clotting
- certain medicines known as **beta blockers**. These are used to treat high blood pressure, heart disease or other illnesses, and have active substance names ending with “olol”
- certain medicines known as **nitrates**, to treat chest pain due to narrowed heart blood vessels, irregular heart beat or high blood pressure
- certain medicines known as **calcium channel blockers**, to treat high blood pressure and certain heart conditions
- certain medicines containing **digitalis**, such as **digoxin**, to treat cardiac failure.

Thallous (Tl201) Chloride with drink

Depending on the type of examination you will receive, it may be necessary to avoid caffeinated drinks for at least 12 hours before the procedure. Your doctor will tell you if this is required in your case.

Pregnancy, breast-feeding and fertility

You must inform the nuclear medicine doctor before the administration of Thallous (Tl201) 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**
The nuclear medicine doctor will **not** administer this product during **pregnancy**, as it could harm the unborn child.
- If you are **breast-feeding**

Tell your doctor if you are breast-feeding as he may **delay the examination** until breast-feeding is finished. If the procedure cannot be postponed, you will have to **stop breast-feeding for 2 days** and discard breast milk, until the radioactivity is no longer in your body.

Please ask your nuclear medicine doctor when you can resume breast-feeding.

Driving and using machines

It is considered unlikely that Thallous (Tl201) Chloride will affect your ability to drive or to use machines.

Thallous (Tl201) Chloride contains sodium

This medicine contains 3.5 mg sodium (main component of table salt/cooking salt) in each ml.

This is equivalent to 0.18 % of the recommended maximum daily dietary intake of sodium for an adult.

3. How Thallous (Tl201) Chloride is used

There are strict laws on the use, handling and disposal of radiopharmaceutical products. Thallous (Tl201) 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 Thallous (Tl201) 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 for an adult ranges from 50 to 110 MBq (megabecquerel, the unit used to express radioactivity).

Administration of Thallous (Tl201) Chloride and conduct of the procedure

Thallous (Tl201) Chloride is administered by injection into a vein.

One injection is usually sufficient to conduct the test that your doctor needs, although sometimes a second injection may be required.

Other tests, like exercise or taking other medicinal products may be part of the procedure.

Duration of the procedure

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

After administration of Thallous (Tl201) 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 Thallous (Tl201) Chloride than you should

An overdose is unlikely because you will only receive a dose of Thallous (Tl201) Chloride precisely controlled by the nuclear medicine doctor supervising the procedure. However, in the case of an overdose, you will receive the appropriate treatment. The nuclear medicine doctor may recommend that you drink plenty of water and urinate frequently to remove the traces of radioactivity from your body.

Should you have any further question on the use of Thallous (Tl201) 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.

Side effects with frequency not known (cannot be estimated from the available data):

- allergic reactions with symptoms such as
 - spasm of the larynx
 - inflammation of the throat
 - swelling at various locations, such as of the face, larynx, tongue
 - breathing difficulties
 - red skin, rash, pustules, itching, nettle-rash, pain of skin
 - hypersensitivity
 - facial pain
 - inflammation of the eye, causing itching, tearing or redness of the eye
 - disturbed flow of tears
 - flushing
 - increased sweating
 - coughing

In case of an allergic reaction you will receive appropriate treatment.

- fainting, or experiencing symptoms such as
 - dizziness
 - slow heart beat
 - low blood pressure
 - shaking
 - headache
 - paleness
- injection site reactions, such as local swelling, pain, redness or other reactions at the site of the injection.
- local tissue damage (necrosis) has been reported in cases where injection was not administered into the vein.

This radiopharmaceutical will deliver low amounts of ionising radiation associated with the least risk of cancer and hereditary abnormalities.

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

HPRA Pharmacovigilance

Website: www.hpra.ie.

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

5. How Thallous (Tl201) 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.

The following information is intended for the specialist only.

Do not store above 25°C.

For storage conditions after first opening of the medicinal product, please refer to the SmPC (section 6.3).

Thallous (Tl201) Chloride must not be used after the expiry date which is stated on the label.

6. Contents of the pack and other information

What Thallous (Tl201) Chloride contains

- The active substance is: Tl201 as thallous chloride.
Each ml contains 37 MBq thallous (Tl201) chloride at the date and time of calibration.
- The other ingredients are: sodium chloride, water for injections and sodium hydroxide or hydrochloric acid for pH adjustment

What Thallous (Tl201) Chloride looks like and contents of the pack

Thallous (Tl201) Chloride is a clear and colourless solution. It is packaged in a 10 ml glass vial closed with a bromobutyl rubber stopper and sealed with an aluminium crimp cap. The vial is supplied in a lead shielding.

Thallous (Tl201) Chloride is supplied in one vial containing:

- 63 MBq (1.7 ml),
- 85 MBq (2.3 ml),
- 213 MBq (5.8 ml) or
- 370 MBq (10 ml)

Marketing Authorisation Holder and Manufacturer

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

The complete SmPC of Thallous (Tl201) Chloride Injection 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.