

PRODUCT  
INFORMATION

## Thallous Chloride [ $^{201}\text{Tl}$ ] Injection

### Description

Thallous Chloride ( $^{201}\text{Tl}$ ) Injection is a sterile solution of thallous chloride ( $^{201}\text{Tl}$ ) in isotonic saline with pH 4.0 to 7.0. The radioactivity at calibration time is 125 MBq per mL. It is essentially carrier free and contains less than 2.0% of  $^{200}\text{Tl}$  and  $^{202}\text{Tl}$ ; greater than 97% of  $^{201}\text{Tl}$  and less than 0.25% lead-203, from supply to customer until expiry. It contains 1.0% benzyl alcohol as a preservative.

### Physical Characteristics

Thallium-201 decays by electron capture with a half-life of 73.1 hours to stable Mercury-201. Photons that are useful for detection and imaging are listed in Table 1. The lower energy X-rays obtained from the Mercury-201 daughter of Thallium-201 are recommended for imaging.

**Table 1: Principal Radiation Emission Data**

Radiation	Mean % per Disintegration	Mean Energy (keV)
Gamma-6	2.7	135.3
Gamma-8	10.0	167.4
Mercury X-rays	93.8	69-83

D A Weber, K E Eckerman, L T Dillman and J C Ryman. "MIRD: Radionuclide Data and Decay Schemes". The Society of Nuclear Medicine Inc., New York, 1989.

**Table 2: Physical Decay Chart for  $^{201}\text{Tl}$**

Hours	Fraction Remaining	Hours	Fraction Remaining
0	1.000	84	0.451
12	0.892	96	0.402
24	0.797	108	0.359
36	0.711	120	0.321
48	0.634	132	0.286
60	0.566	144	0.255
72	0.505		

### External Radiation

The specific gamma ray constant for  $^{201}\text{Tl}$  is 120  $\mu\text{Gy}/\text{MBq}\cdot\text{hr}$  at 1 cm. Attenuation by lead is given in Table 3.

**Table 3: Radiation Attenuation by Lead Shielding**

Shield Thickness(mm)Lead	Coefficient of Attenuation
0.23	0.5
0.83	0.1
1.9	0.01
3.1	0.001

### Actions

Carrier-free thallous chloride ( $^{201}\text{Tl}$ ) has been found to accumulate in viable myocardium in a manner analogous to potassium. Experiments employing labelled microspheres in human volunteers have shown that the myocardial distribution of thallous chloride ( $^{201}\text{Tl}$ )

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correlates well with regional perfusion. In clinical studies, thallium images have been found to visualize areas of infarction confirmed by electrocardiographic and enzyme changes. Regions of transient myocardial ischaemia corresponding to areas perfused by coronary arteries with partial sclerosis have been visualized when thallium was administered in conjunction with an exercise stress test. It is usually not possible to differentiate recent from old myocardial infarction and no exact differentiation can be made between recent myocardial infarction and ischaemia.

After intravenous administration, thallous chloride ( $^{201}\text{Tl}$ ) clears rapidly from the blood with maximal concentration by normal myocardium occurring at about ten minutes.

### Indications

Thallous chloride ( $^{201}\text{Tl}$ ) may be useful in myocardial perfusion imaging for the diagnosis and localization of myocardial infarction.

It may also be useful in conjunction with exercise stress testing as an adjunct in the diagnosis of ischaemic heart disease (atherosclerotic coronary artery disease).

### Contraindications

None known.

### Adverse Reactions

Adverse reactions related to the use of thallous chloride ( $^{201}\text{Tl}$ ) have not been reported to date.

### Warnings

In studying patients in whom myocardial infarction or ischaemia is known or suspected, care should be taken to assure continuous clinical monitoring and treatment in accordance with safe, accepted procedure. Exercise stress testing should be performed only under the supervision of a qualified physician and in a laboratory equipped with appropriate resuscitation and support apparatus.

Factors which attenuate the heart rate response to maximal exercise, such as propranolol or somatic complaints may result in a false negative.

Ideally, examinations using radiopharmaceutical drug products – especially those elective in nature – of women of childbearing capacity should be performed during the first ten days following the onset of menses.

Product contains a preservative and can be used as a multidose injection, however, for microbiological reasons, a breached vial, should be stored at 2 – 8°C.

### Precautions

Data are not available concerning the effect of marked alterations in blood glucose, insulin, or pH (such as is found in diabetes mellitus) on the quality of thallium-201 scans. Attention is directed to the fact that thallium is a potassium analogue, and since the transport of potassium is affected by these factors, the possibility exists that the thallium may likewise be affected.

Thallous chloride ( $^{201}\text{Tl}$ ), as with all radioactive materials, must be handled with care and used with appropriate safety measures to minimize external radiation exposure to clinical personnel.

Care should also be taken to minimize radiation exposure to patients in a manner consistent with proper patient management.

No long-term animal studies have been performed to evaluate carcinogenic potential. Adequate reproduction studies have not been performed in animals to determine whether this drug affects fertility in males or females, has teratogenic potential, or has other adverse effects on the foetus. Thallous chloride ( $^{201}\text{Tl}$ ) should be used in pregnant women only when clearly needed.

It is not known whether this drug is excreted in human milk. As a general rule nursing should not be undertaken when a patient is administered radioactive material.

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Safety and effectiveness in children have not been established. Animal studies indicate that thallium accumulates in the testes. The significance of this observation is not clear.

### Dosage and Administration

As the proportion of ( $^{202}\text{Tl}$ ) contaminant increases (due to its longer half-life) thallous chloride ( $^{201}\text{Tl}$ ) should be used as soon as possible after receipt.

The recommended adult (70 kg) dose of thallous chloride ( $^{201}\text{Tl}$ ) is 40 to 50 MBq. Thallous chloride ( $^{201}\text{Tl}$ ) is intended for intravenous administration only.

For patients undergoing resting thallium studies, imaging is optimally begun within 10–20 minutes after injection. Several investigators have reported improved myocardial-to-background ratios when patients are injected in the fasting state, in an upright posture, or after briefly ambulating.

Best results with thallium imaging performed in conjunction with exercise stress testing appear to be obtained if the thallium is administered when the patient reaches maximum stress and when the stress is continued for 30 seconds to one minute after injection. Imaging should begin within ten minutes post-injection since target-to-background ratio is optimum by that time. Several investigators have reported significant decreases in the target-to-background ratios of lesions attributable to transient ischaemia by two hours after the completion of stress testing.

The patient dose should be measured by a suitable radioactivity calibration system immediately prior to administration.

Radiopharmaceuticals should be used by persons with specific training in the safe use and handling of radionuclides and whose experience and training have been approved by the appropriate government agencies authorised to license the use of radionuclides.

### Radiation Dosimetry

The estimated absorbed radiation dose to adults and children.

Organ	Absorbed Dose per Unit Activity Administered (mGy/MBq)				
	Adult	15 year	10 year	5 year	1 year
Adrenals	5.1E-02	6.6E-02	9.9E-02	1.4E-01	2.5E-01
Bladder wall	3.6E-02	4.8E-02	7.1E-02	1.0E-01	2.0E-01
Bone surfaces	3.4E-01	4.5E-01	7.3E-01	1.3E+00	2.9E+00
Breast	2.8E-02	2.5E-02	4.1E-02	6.4E-02	1.2E-01
GI-tract					
Stomach wall	1.2E-01	1.6E-01	2.4E-01	4.0E-01	7.8E-01
Small intestine	1.6E-01	2.1E-01	3.6E-01	5.7E-01	1.1E+00
* ULI wall	1.9E-01	2.3E-01	4.0E-01	6.5E-01	1.2E+00
* LLI wall	3.6E-01	4.5E-01	7.8E-01	1.3E+00	2.5E+00
* Heart	2.3E-01	2.5E-01	3.9E-01	1.2E+00	2.1E+00
* Kidneys	5.4E-01	6.6E-01	9.4E-01	1.4E+00	2.5E+00
* Liver	1.8E-01	2.2E-01	3.4E-01	5.1E-01	9.6E-01
Lungs	1.2E-01	1.8E-01	2.6E-01	4.1E-01	7.9E-01
Ovaries	1.2E-01	1.3E-01	3.2E-01	5.4E-01	1.2E-01
Pancreas	5.4E-02	6.5E-02	1.0E-01	1.5E-01	2.6E-01
Red marrow	1.8E-01	2.4E-01	3.9E-01	6.9E-01	1.4E+00
Spleen	1.4E-01	1.9E-01	2.9E-01	4.6E-01	8.3E-01
Testes	5.6E-01	1.2E+00	9.7E+00	1.1E+01	1.5E+01
Thyroid	2.5E-01	4.0E-01	6.2E-01	1.4E+00	2.7E+00
Uterus	5.0E-02	5.6E-02	9.1E-02	1.3E-01	2.4E-01
Other tissue	5.6E-02	5.7E-02	9.1E-02	1.5E-01	2.8E-01

Effective dose equivalent (mSv/MBq)

### Impurities

Effective dose equivalent (mSv/MBq of the impurity)

$^{200}\text{Tl}$ (26.1 h)	3.1E-01	4.7E-01	1.2E+00	1.5E+00	2.3E+00
$^{202}\text{Tl}$ (12.23 d)	8.0E-01	1.1E+00	3.1E+00	4.25+00	6.5E+00

Reference: ICRP.53 Radiation Dose to Patients from Radiopharmaceuticals.

# Thallos Chloride [<sup>201</sup>Tl] injection

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## How Supplied

Thallos Chloride (<sup>201</sup>Tl) Injection is a sterile solution of thallos chloride (<sup>201</sup>Tl) in isotonic saline with pH 4.0 to 7.0. The radioactivity at calibration time is 125 MBq (~3 mCi) per mL. It is essentially carrier free and contains <2.0% <sup>202</sup>Tl and less than 0.25% lead-203 from supply to customer until expiry. It contains 1.0% benzyl alcohol as a preservative.

This product is dispensed in 10 mL vials as follows:

- 125 MBq in 1mL )
- 250 MBq in 2 mL )
- 500 MBq in 4 mL )
- 750 MBq in 6 mL )
- 1000 MBq in 8 mL )

## Expiry

Expiry is nominally 120 hours after calibration. The expiry date is printed on the label.

## Storage

Store below 30°C.

Approval Date: July 1992

Amended to comply with BP88 Addendum 90, June 1993 as per TGA request

Catalogue Number

Size	Tuesday Calibration	Thursday Calibration
125MBq	10085	10693
250MBq	10086	10690
500MBq	10087	10691
750MBq	10088	10694
1000MBq	10089	10692

Aust R: 22816

## Contact Details

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ANSTO Radiopharmaceuticals and Industrials (ARI) is a commercial Enterprise of the Australian Nuclear Science Organisation (ANSTO), which is located at Lucas Heights, Sydney.

Revised: May 2008

Date of printing: 27/05/08

