PRODUCT INFORMATION

GENTECH (SODIUM PERTECHNETATE [^{99m}Tc]) INJECTION

1 PRODUCT NAME

Gentech Molybdenum [^{99}Mo]/Technetium [^{99m}Tc] Sterile Generator
For Production of sodium pertechnetate [^{99m}Tc] Injection Multidose Vial.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Description
ANSTO's Gentech® Generator provides a means of obtaining a sterile, isotonic, additive and pyrogen free solution of sodium pertechnetate [^{99m}Tc] Injection (fission) BP. The generator contains fission-product molybdenum-99 [^{99}Mo] from which ^{99m}Tc is separated by elution into evacuated vials.

The generator consists of a sealed glass vessel containing aluminium oxide. The ^{99}Mo is firmly bound to the alumina and as a result, the eluted ^{99m}Tc contains negligible amounts of ^{99}Mo. Over the life of the generator, an elution will provide a yield of approximately 90% of the theoretical amount of ^{99m}Tc available from the ^{99}Mo contained within the generator vessel.

Active Ingredient:
Each vial of eluted solution contains active ^{99m}Tc in 0.9% sodium chloride solution for injections BP.

Excipients: Refer to section 6.1

Physical Characteristics
Technetium-99m [^{99m}Tc], with a physical half-life of 6.02 hours, decays by isometric transition to ^{99}Tc. Photons associated with this transition which are useful for detection and imaging studies are listed in Table 1.

Table-1

Principal Radiation	Mean % per Disintegration	Mean Energy (keV)
Gamma-2	89.1	140.5

Reference: "D A Weber, K F Eckerman, LT Dillman and JC Ryman.MIRD: Radionuclide and Decay Schemes." The Society of Nuclear Medicine Inc., New York, 1989.

External Radiation
The specific gamma ray constant for ^{99m}Tc is 0.19mGy per MBq^{-h-1} at 1cm. The first half value thickness of lead for ^{99m}Tc is 0.2mm. Attenuation by lead is given in the following table.

Table-2

Shield Thicknesses mm Pb	Coefficient of Attenuation (approx.)
0.2	0.5
0.95	10^{-1}
1.8	10^{-2}
2.7	10^{-3}
3.6	10^{-4}

Elution Behaviour

Molybdenum-99, with a half-life of 2.75 days, decays to ^{99m}Tc. The physical decay characteristics of ^{99}Mo are such that 87.5% of its disintegrations form ^{99m}Tc. The decay of ^{99}Mo to ^{99m}Tc occurs until a transient equilibrium is reached when the ^{99m}Tc decay rate equals the rate of its generation, which in turn is proportional to the decay rate of ^{99}Mo, a period of approximately 23 hours. Hence, the activity of ^{99m}Tc available for elution from the generator will depend upon the time interval from the last elution. Table 3 shows the ^{99m}Tc activity for a given growth period following complete elution, relative to the ^{99}Mo activity contained in the generator at the end of the growth period.

Table-3

Growth Periods (hours)	^{99m}Tc:^{99}Mo
1	0.096
2	0.182
4	0.329
8	0.546
24	0.885
48	0.957

Table-4
Physical Decay Chart ^{99}Mo (half-life: 2.75 days)

Days	Fraction Remaining	Days	Fraction Remaining
0	1.000	8	0.1333
1	0.777	9	0.103
2	0.604	10	0.080
3	0.469	11	0.063
4	0.365	12	0.049
5	0.284	13	0.038
6	0.220	14	0.030
7	0.171		

Table-5
Physical Decay Chart ^{99m}Tc (half-life: 6.02 hours)

Hours	Fraction Remaining	Hours	Fraction Remaining
0	1.000	6	0.501
1	0.891	7	0.447
2	0.794	8	0.398
3	0.708	9	0.355
4	0.631	10	0.316
5	0.562		

3 PHARMACEUTICAL FORM

Clear and colourless sodium pertechnetate [^{99m}Tc] solution for I.V. injection eluted from the radionuclide generator.

4 CLINICAL PARTICULARS

4.1 THERAPEUTIC INDICATIONS

This product is for diagnostic use only.
The eluate from the radionuclide generator (sodium pertechnetate [^{99m}Tc] solution for I.V. injection) is indicated for:
- **labelling** of various kits for radiopharmaceutical preparation developed and approved for radiolabelling with such solution
- **Thyroid scintigraphy:** direct imaging and measurement of thyroid uptake to give information on the size, position, nodularity and function of the gland in case of thyroid disease.

4.2 DOSE AND METHOD OF ADMINISTRATION

Posology
If sodium pertechnetate (^{99m}Tc) is administered intravenously, activities may vary widely according to the clinical information required and the equipment employed. The injection of activities greater than local DRLs (Diagnostic Reference Levels) should be justified for certain indications. Recommended activities are as follows:

Adults (70kg) and elderly population
• Thyroid scintigraphy: 20-80 MBq
Renal impairment
Careful consideration of the activity to be administered is required since an increased radiation exposure is possible in these patients.

Paediatric population
The use in children and adolescents has to be considered carefully, based upon clinical needs and assessing the risk/benefit ratio in this patient group.
The activity to be administered to children and adolescents must be adapted <and may be calculated according to the recommendations of the European Association of Nuclear Medicine (EANM) paediatric dosage card>; the activity administered to children and to adolescents may be calculated by multiplying a baseline activity (for calculation purposes) by the weight-dependent correction factor given in the table below (see Table 1).

$$A[MBq]_{Administered} = \text{Baseline Activity} \times \text{Multiple}$$

Thyroid scintigraphy: Activity administered [MBq] = 5.6 MBq x correction factor (Table 6). A minimal activity of 10 MBq is necessary for obtaining images of sufficient quality.

Table 6: Weight-dependent correction factors in the paediatric population (for thyroid scintigraphy) according to the EANM-May 2008 guidelines

Weight [kg]	Multiple	**Weight [kg]**	Multiple	**Weight [kg]**	Multiple
3	1	**22**	5.29	**42**	9.14
4	1.14	**24**	5.71	**44**	9.57
6	1.71	**26**	6.14	**46**	10.00
8	2.14	**28**	6.43	**48**	10.29
10	2.71	**30**	6.86	**50**	10.71
12	3.14	**32**	7.29	**52-54**	11.29

14	3.57	**34**	7.72	**56-58**	12.00
16	4.00	**36**	8.00	**60-62**	12.71
18	4.43	**38**	8.43	**64-66**	13.43
20	4.86	**40**	8.86	**68**	14.00

Method of administration

For intravenous use.
For multidose use.
For instructions on extemporaneous preparation of the medicinal product before administration, see 'Directions for Use'.
For patient preparation, see section 4.4.
In thyroid scintigraphy, the sodium pertechnetate (^{99m}Tc) solution is administered by intravenous injection.

Image acquisition
Thyroid scintigraphy: 20 minutes after intravenous injection.

GENTECH: DIRECTIONS FOR USE

Gentech Molybdenum [^{99}Mo]/Technetium [^{99m}Tc] Sterile Generator

The Gentech® generator is supplied with the following procedure packs -1) saline vials pack containing 0.9% sodium chloride injection BP (saline) vials and sterile wet wipes, and 2) evacuated vials pack containing evacuated elution vials, sterile wet wipes and needles.

The generators are sterile and pyrogen free when they leave ANSTO. To ensure the sterility of the eluate, aseptic techniques must be followed during elution of the Gentech® Compliance to appropriate radiation safety regulations is required for handling generator eluate.

First Elution

1. Remove the Gentech® generator and its accessories from the transport packaging. Install in the Gentech Garage or in the user shielding.

2. Lift Gentech® handle. Rotate the cover until the yellow saline spike cover and elution outlet filter are exposed. Push down handle to lock the lid in the operating position.

3. Remove flip off seal from saline vial (5 or 10 mL). The minimum elution volume is 5 mL. For elution volume between 5 and 10 mL, aseptically remove the unwanted saline from the vial with a hypodermic needle and discard.

4. Place Gentech® saline vial into the **new** Gentech® saline vial holder, provided in the foam insert of the transport package with every generator. Swab the exposed part of the saline vial's silicone septum with a sterile swab provided. **Ensure to allow to dry.**

5. Remove the yellow protective cap from the Gentech® saline spike.

6. Align the lugs of the Gentech® saline vial holder with grooves in the saline port of the Gentech®generator and push down firmly. When vial is fully depressed, turn clockwise in direction of arrows to engage the vial on the saline spike and lock the saline vial holder in place.

7. Remove white plastic lid from the elution vial shield. Unscrew metal top. Remove the red flip-off seal from the 30 mL evacuated elution vial. Place the de-capped vial in the elution vial shield and screw on the metal cap to hold the vial in place. Swab the top of the evacuated elution vial shield and the exposed part of the septum of the evacuated elution vial, with a sterile swab provided. **Ensure to allow to dry.**

8. Grip the red protective cap (male luer closure), turn it anticlockwise through 90° and remove from the outlet filter. With the sterile needle cover in place, attach a sterile needle (screw clockwise). **Caution: do not over-tighten.** Remove the sterile needle cover.

9. Invert the prepared elution vial shield on to the sterile needle. Lower the elution vial shield until the evacuated vial is fully penetrated by the sterile needle. **Allow at least 3 minutes to complete the elution**.

10. Observe emptying of the saline vial and filling of the evacuated elution vial, indicated by the sight and sound of air bubbles in the elution vial.

11. Visibly check the saline vial is empty and through the elution vial shield window that the elution occurred. If elution did not occur, repeat steps 3 and 4 and 6 to 10 with a fresh saline and evacuated elution vials.

12. Remove the elution vial shield from the sterile needle. Cover the elution vial shield with white plastic lid.

13. Place the needle cover back on to the sterile needle and leave it in place until the next elution. (Replace with a fresh sterile needle before each elution).

14. **Do not remove saline vial assembly until the next elution**.

15. Record the appropriate information on the elution vial in accordance with your facility procedures, such as date, time and the contents being radioactive.

16. Assay the contents of the vial, for its ^{99m}Tc contents using a previously calibrated ^{99m}Tc dose calibrator (or other suitable measuring instrument). Calculate the total ^{99m}Tc content of the vial. Record the results.

17. Perform a gamma spectroscopy test to determine extent of 99Mo breakthrough. Alternate method described by *Richards and O'Brien may be used.

Subsequent Elutions

1. Remove the used saline vial (by twisting anti-clockwise), then repeat steps 3, 4, and 6, 7.

2. Remove used elution needle (by twisting anti-clockwise) and replace with a fresh sterile elution needle.

3. Repeat steps 9 through to 17.

Troubleshooting tips when the Generator is not eluting

1. Check that the elution needle is not loose (see step 8).

2. Try another evacuated vial.

3. If you inadvertently remove the elution vial before it finishes eluting, the column will have become wet and will need to be dried. Attach a fresh evacuated vial but do not replace the saline vial unless it still contains some saline. In this case replace it with an empty saline vial. This process will allow air and not saline, to pass through and this will dry off the column. This process using an empty saline vial and a new evacuated elution vial can be repeated to ensure the column is dry.

4. Contact your local sales representative.

To Prevent Damaging the Spike

1. Use a new Gentech® saline vial holder, provided with every new generator in the foam insert of the packaging of every new Gentech® generator.

2. Ensure the protective flip off seal is removed from the saline vial.

3. Ensure the lid of the Gentech® generator garage is fully open, to allow clear access to the Gentech® generator.
4. Ensure the yellow protective cap is removed from the saline spike.
5. Ensure the saline vial is placed on the spike vertically and not at an angle.
6. Following swabbing of the silicon septum of the saline vial, ensure to allow to dry.

*Reference: *Richards, P. and O'Brien, M.J., Rapid determination of ^{99}Mo in separated ^{99m}Tc. J. Nucl. Med., 10:517, 1969.*

4.3 CONTRAINDICATIONS

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE

General

Radiopharmaceuticals should be used only by physicians who are qualified by specific training in the safe use and handling of radionuclides produced by a nuclear reactor or particle accelerator and whose experience and training have been approved by the appropriate government agency authorised to license the use of radionuclides.

Care should be taken to minimise radiation exposure to patients consistent with proper patient management. As with other radioactive drugs, sodium pertechnetate [^{99m}Tc] must be handled with care and appropriate safety measures should be used to minimise radiation exposure to clinical personnel.

Disposal of all radioactive wastes should be carried out in accordance with local requirements.

Potential for hypersensitivity or anaphylactic reactions

If hypersensitivity or anaphylactic reactions occur, the administration of the medicinal product must be discontinued immediately and intravenous treatment initiated, if necessary. To enable immediate action in emergencies, the necessary medicinal products and equipment such as endotracheal tube and ventilator must be immediately available.

Individual benefit/risk justification

For each patient, the radiation exposure must be justifiable by the likely benefit. The activity administered should in every case be as low as reasonably achievable to obtain the required diagnostic information.

Renal impairment

Careful consideration of the benefit risk ratio in these patients is required since an increased radiation exposure is possible.

Paediatric population

For information on the use in paediatric population, see section 4.2.

Careful consideration of the indication is required since the effective dose per MBq is higher than in adults (see section 10).

Patient preparation

The patient should be well hydrated before the start of the examination and urged to void as often as possible during the first hours after the examination in order to reduce radiation.

To avoid false positives or to minimise irradiation by reduction of pertechnetate accumulation in the thyroid glands, a thyroid blocking agent must NOT be used before thyroid scintigraphy.

After the procedure

Close contact with infants and pregnant women should be restricted during 12 hours.

Specific warnings

Sodium pertechnetate (^{99m}Tc) solution for injection contains 3.5 mg/mL of sodium.

Depending on the time when the injection is administered, the content of sodium given to the patient may in some cases be greater than 1 mmol (23 mg). This should be taken into account in patient on low sodium diet.

When sodium pertechnetate (^{99m}Tc) solution is used for labelling of a kit, the determination of the overall sodium content must take into account the sodium derived from the eluate and the kit. Please refer to the package leaflet of the kit.

Use in the elderly

No data available.

Paediatric use

No data available.

Effects on laboratory tests

No data available.

4.5 INTERACTIONS WITH OTHER MEDICINES AND OTHER FORMS OF INTERACTIONS

In abdominal imaging, drugs such as atropine, isoprenaline and analgesics can result in a delay in gastric emptying and redistribution of pertechnetate.

Many pharmacological medicinal products are known to modify the thyroid uptake.

- antithyroid medicinal products (e.g. carbimazole or other imidazole derivatives such as propylthiouracil), salicylates, steroids, sodium nitroprusside, sodium sulfobromophtalein, perchlorate should be withheld for 1 week prior thyroid scintigraphy ;
- phenylbutazone and expectorants should be withheld for 2 weeks ;
- natural or synthetic thyroid preparations (e.g. sodium thyroxine, sodium liothyronine, thyroid extract) should be withheld for 2-3 weeks
- amiodarone, benzodiazepines, lithium should be withheld for 4 weeks
- intravenous contrast agents should not have been administered within 1-2 months.

4.6 FERTILITY, PREGNANCY AND LACTATION

Women of childbearing potential

When an administration of radiopharmaceuticals to a woman of childbearing potential is intended, it is important to determine whether or not she is pregnant. Any woman who has missed a period should be assumed to be pregnant until proven otherwise. If in doubt about her potential pregnancy (if the woman has missed a period, if the period is very irregular, etc.), alternative techniques not using ionising radiation (if there are any) should be offered to the patient.

Pregnancy

Administration of pertechnetate (^{99m}Tc) to a woman who is known to be pregnant should be justified by medical need and a positive individual benefit risk assessment for the mother and the foetus. Alternative non-irradiating diagnostic modalities should be taken into account.

^{99m}Tc (as free pertechnetate) has been shown to cross the placental barrier.

Breast-feeding

Before administering radiopharmaceuticals to a mother who is breast-feeding, consideration should be given to the possibility of delaying the administration of radionuclide until the mother has ceased breast-feeding and to what is the most appropriate choice of radiopharmaceuticals, bearing in mind the secretion of activity in breast milk. If the administration is considered necessary, breast-feeding should be interrupted for 12 hours post administration and the expressed feeds discarded.

Close contact with infants should be restricted during this period.

4.7 EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

Sodium pertechnetate (^{99m}Tc) solution has no influence on the ability to drive and use machines.

4.8 ADVERSE EFFECTS (UNDESIRABLE EFFECTS)

Summary of the safety profile

Information on adverse reactions is available from spontaneous reporting. The reported reaction types are anaphylactoid reactions, vegetative reactions, as well as different kinds of injection site reactions. Sodium pertechnetate (^{99m}Tc) from the {(Invented) name} radionuclide generator is used for radioactive labelling of a variety of compounds. These medicinal products generally have a higher potential for adverse reactions than ^{99m}Tc, and therefore the reported adverse reactions are rather related to the labelled compounds than to ^{99m}Tc. The possible types of adverse reactions following intravenous administration of a ^{99m}Tc-labelled pharmaceutical preparation will be dependent on the specific compound being used. Such information can be found in the SmPC of the kit used for radiopharmaceutical preparation.

Tabulated list of adverse reactions

The frequency of undesirable effects is defined as follows:

Not known (cannot be estimated from the available data).

Immune system disorders

Frequency unknown*: Anaphylactoid reactions (e.g. dyspnoea, coma, urticaria, erythema, rash, pruritus, oedema at various location e.g. face oedema)

Nervous system disorders

Frequency unknown*: Vasovagal reactions (e.g. syncope, tachycardia, bradycardia, dizziness, headache, vision blurred, flushing)

Gastrointestinal disorders

Frequency unknown*: Vomiting, nausea, diarrhoea

General disorders and administration site conditions

Frequency unknown*: Injection site reactions due to extravasation (e.g. cellulitis, pain, erythema, swelling)

* Adverse reactions derived from spontaneous reporting

Exposure to ionising radiation is linked with cancer induction and a potential for development of hereditary defects. As the effective dose is 5.2 mSv when the maximal recommended activity of 400 MBq is administered these adverse reactions are expected to occur with a low probability.

Description of selected adverse reactions

Anaphylactic reactions (e.g. dyspnoea, coma, urticaria, erythema, rash, pruritus, oedema at various locations [e.g. face oedema])

Anaphylactic reactions have been reported following intravenous injection of sodium perchtechnetate (^{99m}Tc) and include various skin or respiratory symptoms like skin irritations, oedema, or dyspnoea.

Vegetative reactions (nervous system and gastrointestinal disorders)

Single cases of severe vegetative reactions have been reported, however, most of the reported vegetative reactions include gastrointestinal reactions like nausea or vomiting. Other reports include vasovagal reactions like headache or dizziness. Vegetative reactions are rather considered to be related to the examinational setting than to technetium (^{99m}Tc), especially in anxious patients.

General disorders and administration site conditions

Other reports describe local injection site reactions. Such reactions are related to extravasation of the radioactive material during the injection, and the reported reactions rank from local swelling up to cellulitis. Depending on the administered radioactivity and the labeled compound, extended extravasation may necessitate surgical treatment.

4.9 OVERDOSE

In the event of administration of a radiation overdose with sodium pertechnetate (^{99m}Tc), the absorbed dose should be reduced where possible by increasing the elimination of the radionuclide from the body by defaecation, forced diuresis and frequent bladder voiding.

5 PHARMACOLOGICAL PROPERTIES

5.1 PHARMACODYNAMIC PROPERTIES

The ATC code of Gentech Generator is:
Diagnostic radiopharmaceuticals, various thyroid diagnostic radiopharmaceuticals.
ATC code: V09F X01

At diagnostic doses sodium pertechnetate [^{99m}Tc] does not exhibit clinically and/or analytically noticeable pharmacodynamic effects.

Mechanism of action

Not applicable.

Clinical trials

Not applicable.

5.2 PHARMACOKINETIC PROPERTIES

Distribution

The pertechnetate ion has similar biological distribution to iodide and perchlorate ions, concentrating temporarily in salivary glands, choroid plexus, stomach (gastric mucosa) and in the thyroid gland, from which it is eliminated, unchanged. The pertechnetate ion also tends to concentrate in areas with increased vascularisation or with abnormal vascular permeability, particularly when pre-treatment with blocking agents inhibits uptake in glandular structures. With intact blood brain barrier, sodium pertechnetate (^{99m}Tc) does not penetrate into the brain tissue.

Organ uptake

In the blood 70-80% of the intravenously injected sodium pertechnetate (^{99m}Tc) is bound to proteins, primarily in an unspecific way to albumin. The unbound fraction (20-30%) accumulates temporarily in thyroid and salivary glands, stomach and nasal mucous membranes as well as in the plexus chorioideus.

Sodium pertechnetate (^{99m}Tc) in contrast to iodine, nevertheless, is neither used for the thyroid hormone synthesis (organification), nor absorbed in the small intestine. In the thyroid the maximum accumulation, depending on functional status and iodine saturation (in euthyroidism approx. 0.3-3%, in hyperthyroidism and iodine depletion up to 25%) is reached about 20 min after injection and then decreases quickly. This also applies for the stomach mucous membrane parietal cells and the salivary glands acinar cells.

In contrast to the thyroid which releases sodium pertechnetate (^{99m}Tc) in the bloodstream the salivary glands and the stomach secrete sodium pertechnetate (^{99m}Tc) in the saliva and gastric juice, respectively. The accumulation by the salivary gland lies in the magnitude of 0.5% of the applied activity with the maximum reached after about 20 minutes. One hour after injection, the concentration in the saliva is about 10-30 fold higher than in the plasma. The excretion can be accelerated by lemon juice or by stimulation of the parasympathetic nerve system, the absorption is reduced by perchlorate.

Elimination

Half life in plasma is approximately 3 hours. Sodium pertechnetate (^{99m}Tc) is not metabolised in the organism. One fraction is eliminated very quickly renally, the rest more slowly via faeces, salivary and tear liquid. Excretion during the first 24 hours following administration is mainly urinary (approximately 25%) with faecal excretion occurring over the next 48 hours. Approximately 50% of the administered activity is excreted within the first 50 hours. When selective uptake of pertechnetate (^{99m}Tc) in glandular structures is inhibited by the pre-administration of blocking agents, excretion follows the same pathways but there is a higher renal clearance.

The above data are not valid when sodium pertechnetate (^{99m}Tc) is used for labelling of another radiopharmaceutical.

5.3 PRECLINICAL SAFETY DATA

There is no information on acute, subacute and chronic toxicity from single or repeated dose administration. The quantity of sodium pertechnetate (^{99m}Tc) administered during clinical diagnostic procedures is very small and, apart from allergic reactions, no other adverse reactions have been reported.

This medicinal product is not intended for regular or continuous administration.

Mutagenicity studies and long-term carcinogenicity studies have not been carried out.

Reproductive toxicity

Placental transfer of ^{99m}Tc from intravenously administered sodium pertechnetate (^{99m}Tc) has been studied in mice. The pregnant uterus was found to contain as much as 60% of the injected ^{99m}Tc when administered without perchlorate pre-administration. Studies performed on pregnant mice during gestation, gestation and lactation, and lactation alone showed changes in progeny which included weight reduction, hairlessness and sterility.

6 PHARMACEUTICAL PARTICULARS

6.1 LIST OF EXCIPIENTS

Sodium Chloride, BP
Water for Injections, BP

6.2 INCOMPATIBILITIES

This medicinal product must not be mixed with other medicinal products except with those as required to achieve therapeutic indications given in Section 4 of this Product Information document.

Interaction of this medicine with others is also given in Section 4.5 of this Product Information document.

6.3 SHELF LIFE

The expiry date can be found on the packaging.

Note:

(i) Eluate from generators, Sodium Pertechnetate [^{99m}Tc] Injection does not contain an antimicrobial preservative, hence should only be used within 8 hours after elution.

6.4 SPECIAL PRECAUTIONS FOR STORAGE

Storage
The generator is designed to operate at normal room temperature (below 30°C).

6.5 NATURE AND CONTENTS OF CONTAINER

Borosilicate glass column contains alumina on which molybdic [^{99}Mo] acid is bound and decays to sodium pertechnetate [^{99m}Tc]. The glass column is housed in a lead shield contained within a plastic chassis.

Sodium pertechnetate [^{99m}Tc] injection is eluted into a 30mL brown tinted evacuated vial housed within a shield.

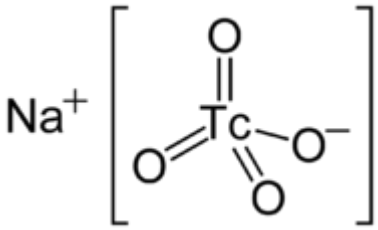
6.6 SPECIAL PRECAUTIONS FOR DISPOSAL

Disposal of the Generator
The generator (and packaging) should be kept and not disposed of as normal waste within 70 days of the calibration date. Users are encouraged to return their generators to ANSTO for recycling. A special set of instructions and labels are included with each generator.

Refer to Section 4.4 - Special warnings and precautions for use.

6.7 PHYSICOCHEMICAL PROPERTIES

Chemical structure:



CAS number:
23288-60-0

7 HOW SUPPLIED

The generator is supplied in sizes ranging from 10 to 120 GBq and 370 GBq of 99Mo at 0900 hours Sydney time on the day of calibration.

The generator pack contains the following items for use in its elution:
(i) 1 Sterile generator.
(ii) 2 kits each containing 5x5mL or 5x10mL or 5x20mL vials of Sodium Chloride for Injections BP.
(iii) 2 kits each containing 5 x 30 evacuated vials, 5 sterile needles and 5 sterile mediswabs.
(iv) Elution vial shield with viewing window supplied with initial order only.

Not all presentations may be available locally.

8 PRODUCT REGISTRANT

Transmedic Pte Ltd
5 Jalan Kilang Barat, #09-00 Floor Petro Centre,
Singapore 159349

9 DATE OF REVISION

16 Feb 2021

10 DOSIMETRY

The data listed below are from ICRP 80 and are calculated according to the following assumptions:

(I) Without pre-treatment with a blocking agent:

Organ	**Absorbed dose per administered unit of activity (mGy/MBq)**				
	Adults	**15 years**	**10 years**	**5 years**	**1 year**
Adrenal glands	0.0037	0.0047	0.0072	0.011	0.019
Bladder wall	0.018	0.023	0.030	0.033	0.060
Bone surfaces	0.0054	0.0066	0.0097	0.014	0.026
Brain	0.0020	0.0025	0.0041	0.0066	0.012
Breasts	0.0018	0.0023	0.0034	0.0056	0.011
Gallbladder	0.0074	0.0099	0.016	0.023	0.035
Gastrointestinal tract					
- Stomach wall	0.026	0.034	0.048	0.078	0.16
- Small intestine	0.016	0.020	0.031	0.047	0.082
- Colon	0.042	0.054	0.088	0.14	0.27
- Ascending colon wall	0.057	0.073	0.12	0.20	0.38
- Descending colon wall	0.021	0.028	0.045	0.072	0.13
Heart	0.0031	0.0040	0.0061	0.0092	0.017
Kidneys	0.0050	0.0060	0.0087	0.013	0.021
Liver	0.0038	0.0048	0.0081	0.013	0.022
Lungs	0.0026	0.0034	0.0051	0.0079	0.014
Muscles	0.0032	0.0040	0.0060	0.0090	0.016
Oesophagus	0.0024	0.0032	0.0047	0.0075	0.014
Ovaries	0.010	0.013	0.018	0.026	0.045
Pancreas	0.0056	0.0073	0.011	0.016	0.027
Red bone marrow	0.0036	0.0045	0.0066	0.0090	0.015
Salivary glands	0.0093	0.012	0.017	0.024	0.039
Skin	0.0018	0.0022	0.0035	0.0056	0.010
Spleen	0.0043	0.0054	0.0081	0.012	0.021
Testes	0.0028	0.0037	0.0058	0.0087	0.016
Thymus	0.0024	0.0032	0.0047	0.0075	0.014
Thyroid	0.022	0.036	0.055	0.12	0.22
Uterus	0.0081	0.010	0.015	0.022	0.037
Other tissue	0.0035	0.0043	0.0064	0.0096	0.017

Effective dose (mSv/MBq)	**0.013**	**0.017**	**0.026**	**0.042**	**0.079**

(II) With pre-treatment with a blocking agent:

Organ	**Absorbed dose per administered unit of activity (mGy/MBq) when blocking agents are administered**				
	Adults	**15**	**10**	**5**	**1**
Adrenal glands	0.0029	0.0037	0.0056	0.0086	0.016
Bladder wall	0.030	0.038	0.048	0.050	0.091
Bone surfaces	0.0044	0.0054	0.0081	0.012	0.022
Brain	0.0020	0.0026	0.0042	0.0071	0.012
Breasts	0.0017	0.0022	0.0032	0.0052	0.010
Gallbladder	0.0030	0.0042	0.0070	0.010	0.013
Gastrointestinal tract					
- Stomach wall	0.0027	0.0036	0.0059	0.0086	0.015
- Small intestine	0.0035	0.0044	0.0067	0.010	0.018
- Colon	0.0036	0.0048	0.0071	0.010	0.018
- Ascending colon	0.0032	0.0043	0.0064	0.010	0.017
- Descending colon	0.0042	0.0054	0.0081	0.011	0.019
Heart	0.0027	0.0034	0.0052	0.0081	0.014
Kidneys	0.0044	0.0054	0.0077	0.011	0.019
Liver	0.0026	0.0034	0.0053	0.0082	0.015
Lungs	00023	0.0031	0.0046	0.0074	0.013
Muscles	0.0025	0.0031	0.0047	0.0072	0.013
Oesophagus	0.0024	0.0031	0.0046	0.0075	0.014
Ovaries	0.0043	0.0054	0.0078	0.011	0.019
Pancreas	0.0030	0.0039	0.0059	0.0093	0.016
Red bone marrow	0.0025	0.0032	0.0049	0.0072	0.013
Skin	0.0016	0.0020	0.0032	0.0052	0.0097
Spleen	0.0026	0.0034	0.0054	0.0083	0.015
Testes	0.0030	0.0040	0.0060	0.0087	0.016
Thymus	0.0024	0.0031	0.0046	0.0075	0.014
Thyroid	0.0024	0.0031	0.0050	0.0084	0.015
Uterus	0.0060	0.0073	0.011	0.014	0.023
Other tissue	0.0025	0.0031	0.0048	0.0073	0.013
Effective dose (mSv/MBq)	**0.0042**	**0.0054**	**0.0077**	**0.011**	**0.019**

The effective dose resulting from the intravenous administration of 400 MBq of sodium pertechnetate (^{99m}Tc) to an adult weighing 70 kg is about 5.2 mSv.

After pretreatment of patients with a blocking agent and administration of 400 MBq of sodium pertechnetate (^{99m}Tc) to an adult weighing 70 kg the effective dose is 1.7 mSv.

The radiation dose absorbed by the lens of the eye following administration of sodium pertechnetate (^{99m}Tc) for lacrimal duct scintigraphy is estimated to be 0.038 mGy/MBq. This results in an effective dose equivalent of less than 0.01 mSv for an administered activity of 4 MBq.

The specified radiation exposure is only applicable if all organs accumulating sodium pertechnetate (^{99m}Tc) will function normally. Hyper/hypofunction (e.g. of the thyroid, gastric mucosa or kidney) and extended processes with impairment to the blood-brain-barrier or renal elimination disorders, may result in changes to the radiation exposure, locally even in strong increases of it.

The surface dose rates and the accumulated dose depends on many factors. Overall, radiation measurement on the environment and during work are critical and should be practised.