Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

TechneScan DTPA 20.8 mg kit for radiopharmaceutical preparation

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each vial contains:

Pentetic acid 20.8 mg
To be reconstituted with sodium pertechnetate (^{99m}Tc) for the preparation of the diagnostic agent: Technetium (^{99m}Tc) pentetate. The radionuclide is not part of the kit.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Kit for radiopharmaceutical preparation.
Off White to slightly yellow freeze-dried powder for solution for injection, oral use or inhalation.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

This medicinal product is for diagnostic use only.

After reconstitution with sodium pertechnetate (^{99m}Tc) solution, the solution of technetium (^{99m}Tc) pentetate is indicated for:

a) After intravenous administration for:

- Measurement of glomerular filtration rate
- Renal perfusion and function and urinary tract studies
- Cerebral angioscintigraphy (as an alternative method when computed tomography and/or magnetic resonance imaging are not available)

b) After inhalation of the nebulized technetium (^{99m}Tc) pentetate for:

- Lung ventilation imaging

c) After oral administration of the technetium (^{99m}Tc) pentetate for:

- Detection of gastroesophageal reflux and gastric emptying study

4.2 Posology and method of administration

Posology
In adults and the elderly population, the following administered activities are recommended (other doses may be justifiable):

For intravenous use

- Measurement of glomerular filtration rate from plasma: 7-18 MBq.
- Renal scintigraphy: 40-400 MBq.
- Cerebral angioscintigraphy: 185-740 MBq.

For inhalation

- Lung ventilation imaging: 500-1000 MBq deposited in the nebuliser; 50-100 MBq in the lung.

For oral use

- Detection of gastroesophageal reflux and liquid gastric emptying study: 10-20 MBq. Technetium (^{99m}Tc) pentetate is mixed with an appropriate volume (30 to 240 mL) of liquid carrier (e.g. milk).

Renal/hepatic impairment

Careful consideration of the activity to be administered is required since an increased radiation exposure is possible in these patients (see section 4.4).

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 activities to be administered by intravenous route to children and to adolescents may be calculated according to the recommendations of the European Association of Nuclear Medicine EANM (2016) paediatric dosage card, by using the formula corresponding to the concerned indication and the relevant correction factor corresponding to the body mass of the young patient.

- Administration of technetium (^{99m}Tc) pentetate in abnormal renal function:
Administered Activity[MBq] = Baseline Activity x Multiple (with a baseline activity of 14.0)

Table 1

Body Mass	**Multiple**	Body Mass	**Multiple**	Body Mass	**Multiple**
3 kg	**1**	22 kg	**5.29**	42 kg	**9.14**
4 kg	**1.14**	24 kg	**5.71**	44 kg	**9.57**
6 kg	**1.71**	26 kg	**6.14**	46 kg	**10.00**
8 kg	**2.14**	28 kg	**6.43**	48 kg	**10.29**
10 kg	**2.71**	30 kg	**6.86**	50 kg	**10.71**
12 kg	**3.14**	32 kg	**7.29**	52-54 kg	**11.29**
14 kg	**3.57**	34 kg	**7.72**	56-58 kg	**12.00**
16 kg	**4.00**	36 kg	**8.00**	60-62 kg	**12.71**
18 kg	**4.43**	38 kg	**8.43**	64-66 kg	**13.43**
20 kg	**4.86**	40 kg	**8.86**	68 kg	**14.00**

In very young children (up to 1 year), when technetium (^{99m}Tc) pentetate is used for urinary tract examinations, a minimum dose of 20 MBq is necessary to obtain images of sufficient quality.

- Administration of technetium (^{99m}Tc) pentetate in normal renal function:
Administered Activity[MBq] = Baseline Activity x Multiple (with a baseline activity of 34.0)

Table 2

Body Mass	**Multiple**	Body Mass	**Multiple**	Body Mass	**Multiple**
3 kg	**1**	22 kg	**3.06**	42 kg	**4.41**
4 kg	**1.12**	24 kg	**3.18**	44 kg	**4.53**
6 kg	**1.47**	26 kg	**3.35**	46 kg	**4.65**
8 kg	**1.71**	28 kg	**3.47**	48 kg	**4.77**
10 kg	**1.94**	30 kg	**3.65**	50 kg	**4.88**
12 kg	**2.18**	32 kg	**3.77**	52-54 kg	**5.00**
14 kg	**2.35**	34 kg	**3.88**	56-58 kg	**5.24**
16 kg	**2.53**	36 kg	**4.00**	60-62 kg	**5.47**
18 kg	**2.71**	38 kg	**4.18**	64-66 kg	**5.65**
20 kg	**2.88**	40 kg	**4.29**	68 kg	**5.77**

Lung ventilation imaging: 500 - 1000 MBq deposited in the nebuliser; 10 MBq in the lung.

Detection of gastroesophageal reflux and liquid gastric emptying study:

10 - 20 MBq. Administered activity of the radiopharmaceutical and the volume to be fed to the patient should be based on patient factors such as age, body weight, and the usual feeding volume. Administered activity for children should be as low as reasonably achievable for diagnostic image quality.

Method of administration

For intravenous, inhalation and oral administration.

For multidose use.

This medicinal product should be reconstituted before administration to the patient.

For instructions on reconstitution and radiolabelling of the medicinal product before administration, see section 12.

For patient preparation, see section 4.4.

Image acquisition

- Renal perfusion imaging is obtained by dynamic acquisitions immediately after injection up to 1 minute. The optimal static imaging time is 1 hour post injection. In case of captopril (ACE inhibitor) renography, captopril is given intravenously before technetium (^{99m}Tc) pentetate administration. Individual kidney function and urinary outflow imaging are obtained by dynamic acquisitions performed after injection. If one or both kidneys have not emptied satisfactorily during the first 20 minutes, a furosemide challenge is performed and the dynamic acquisition should continue for a further 15-minute after the diuretic. Static images may be acquired 1 hour after injection.
- For cerebral examinations, dynamic acquisitions should begin immediately after injection. Static images are obtained 1 hour and, if necessary, several hours after injection.
- For lung ventilation imaging: images of the lungs are obtained during 180 min.
- Dynamic images of oesophagus are obtained during the first minutes after administration followed by continuous imaging for 60 minutes for evaluation of gastroesophageal reflux. Gastric emptying at 60 minutes and at 2 or 3 hours after completion of feeding is calculated.

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

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 administrated should in every case be as low as reasonably achievable to obtain the required diagnostic information.

Renal/ hepatic 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 use in the 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 11).

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.

Specific warnings
TechneScan DTPA must not be administered into the subarachnoidal space as it should not be used for scintigraphy of the cerebrospinal flow.

Depending on the time when you administer the injection, the content of sodium given to the patient may in some cases be greater than 1mmol. This should be taken into account in patients on low sodium diet.

4.5 Interaction with other medicinal products and other forms of interaction

Many drugs may affect the function of the tested organ and modify the uptake of technetium (^{99m}Tc) pentetate;

During renal scintigraphy
A single administration of a diuretic or ACE inhibitor is sometimes used during pharmacological tests in the differential diagnosis of nephrological and urological disorders.

ACE inhibitors reduce renal blood flow.
Diclofenac, furosemide and other diuretics such as hydrochlorothiazide may affect renal excretion and thereby influence the technetium (^{99m}Tc) pentetate clearance.
Nephrotoxic drugs such as aminoglycosides, cisplatin and administered contrast media can reduce the renal excretion and thereby influence the technetium (^{99m}Tc) pentetate clearance.

During gastroesophageal scintigraphy and gastric emptying

- Morphine and levodopa delay gastric emptying.
- Metoclopramide may stimulate gastric emptying and decrease significantly the small intestine transit time.
- Aluminium antacids and propantheline may prolong the gastric emptying.

During cerebral angioscintigraphy
Psychotropic medications increase blood flow in the area of the external carotid artery. This may lead to the rapid uptake of the radioactive product in the nasopharyngeal area during the arterial and capillary phases ("hot nose" phenomenon).

4.6 Fertility, pregnancy and lactation

Women of childbearing potential
When 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
Radionuclide procedures carried out on pregnant women also involve radiation dose to the foetus. Only essential investigations should therefore be carried out during pregnancy, when the likely benefit far exceeds the risk incurred by the mother and foetus.

Breast-feeding
Before administering radiopharmaceuticals to a mother who is breast-feeding consideration should be given as 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, the breast-feeding should be interrupted for 12 hours and the expressed feeds discarded.

Fertility
No study on fertility has been performed.

4.7 Effects on ability to drive and use machines

Technetium (^{99m}Tc) pentetate has no or negligible influence on the ability to drive and use machines.

4.8 Undesirable effects

The adverse events are presented in the table below by system organ classes and with a not known frequency (cannot be estimated from the available data).

System Organ Class	Symptom	Frequency
Nervous system disorders	Dizziness	Not known
Respiratory, thoracic and mediastinal disorders	Dyspnoea	Not known
Skin and subcutaneous tissue disorders	Urticaria, pruritus	not known
Vascular disorders	Hypotension, Flushing	Not known

Exposure to ionising radiation is linked with cancer induction and a potential for development of hereditary defects. As the effective dose is 3.6 mSv when the maximal recommended activity of 740 MBq is administered these adverse events are expected to occur with a low probability.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via HPRA Pharmacovigilance, Website: www.hpra.ie.

4.9 Overdose

In the event of the administration of a radiation overdose with technetium (^{99m}Tc) pentetate the absorbed dose to the patient should be reduced where possible by increasing the elimination of the radionuclide from the body by forced diuresis and frequent bladder voiding. It might be helpful to estimate the effective dose that was applied.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Diagnostic radiopharmaceuticals for the renal and respiratory systems, Technetium (^{99m}Tc) compounds.
ATC Code: V09CA01; V09EA01

Mechanism of action:

- Technetium(^{99m}Tc) pentetate, like inulin, circulates in blood with negligible binding to plasma proteins. It is filtered through the glomerular membrane and undergoes no tubular secretion or reabsorption. It does not cross the normal blood-brain barrier (BBB).
- Technetium(^{99m}Tc) pentetate is aerosolised from a water solution with a particle size of 1.2 - 2 micrometres. After inhalation aerosol droplets are distributed and deposited within airways and alveoli depending on their aerodynamic properties, particularly their mass median aerodynamic diameter.
- Following oral administration, technetium (^{99m}Tc) pentetate does not pass through the digestive barrier (non-absorbable). Mixed with the meal, technetium (^{99m}Tc) pentetate follows digestive transit.

Pharmacodynamic effects:
At the concentrations and activities such as those used for diagnosis, ^{99m}Tc pentetate does not appear to have any pharmacodynamic activity.

5.2 Pharmacokinetic properties

Distribution
Following intravenous injection, technetium (^{99m}Tc) pentetate rapidly distributes throughout the extracellular space. Less than 5% of the injected dose is bound to plasma proteins. There is also negligible binding of technetium (^{99m}Tc) pentetate to red blood cells. Technetium (^{99m}Tc) pentetate does not cross the normal blood-brain barrier but diffuses weakly in breast milk.
In patients exhibiting oedema or ascites, distribution of the radioisotope in the extracellular space may be modified.

In lung ventilation studies, following inhalation, technetium (^{99m}Tc) pentetate diffuses rapidly from the lung alveoli towards the vascular space where it is diluted. Many factors are likely to modify the permeability of the pulmonary epithelium such as cigarette smoking.
Following oral administration, technetium (^{99m}Tc) pentetate does not pass through the digestive barrier.

Elimination
Plasma clearance is multiexponential with an extremely fast component. The complex remains stable *in vivo*. More than 98% of urine radioactivity is in the form of a chelate. Approximately 90% of the injected dose is eliminated in the urine within the first 24 hours, mainly by glomerular filtration. No retention of the compound has been demonstrated in the kidneys.

Half-life
The physical half-life of technetium (^{99m}Tc) is 6.01 hours.
The half-life of technetium (^{99m}Tc) pentetate in the lungs is slightly less than 1 hour.

Renal/Hepatic impairment
Plasma clearance may be delayed in patients with kidney disease.
The pharmacokinetics in patients with hepatic impairment has not been characterised.

5.3 Preclinical safety data

This medicinal product is not intended for regular or continuous administration. Repeated intravenous administration of $CaNa_3DTPA$ to rabbits and dogs for 14 days of doses that were 100 and 1000 times (respectively) the normal dose for humans produced no evidence of toxicity. The minimum dose of CaDTPA causing abortion and fetal death in mice was approximately 3600 times the dose of $CaNa_3DTPA$ that is proposed for diagnosis in women. Mutagenicity studies and long-term carcinogenicity studies have not been carried out.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Gentisic acid
Stannous chloride dihydrate
Calcium chloride dihydrate
Sodium hydroxide
Hydrochloric acid (for pH adjustment)

6.2 Incompatibilities

This medicinal product must not be mixed with other medicinal products except those mentioned in section 12.

6.3 Shelf life

1 year when stored below 25°C
The expiry date is stated on the label of each vial and on the carton box.
After radiolabelling 8 hours when stored below 25°C.

6.4 Special precautions for storage

Keep the vials in the outer carton.
For storage conditions after radiolabelling of the medicinal product, see section 6.3.
Storage of radiopharmaceuticals should be in accordance with national regulations for radioactive materials.

6.5 Nature and contents of container

Carton box containing five 10 mL (Type 1 Ph.Eur.) glass vials closed with a bromobutyl rubber lyophilisation stopper sealed with an aluminium cap.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

General warning
Radiopharmaceuticals should be received, used and administered only by authorised persons in designated clinical settings. Their receipt, storage, use, transfer and disposal are subject to the regulations and/or appropriate licences of the competent official organisation.

Radiopharmaceuticals should be prepared in a manner which satisfies both radiation safety and pharmaceutical quality requirements. Appropriate aseptic precautions should be taken.

Contents of the kit are intended only for use in the preparation of technetium (^{99m}Tc) pentetate and are not to be administered directly to the patient without first undergoing the preparative procedure.

For instructions on reconstitution of the medicinal product before administration, see section 12.

If at any time in the preparation of this product the integrity of this vial is compromised it should not be used.
Administration procedures should be carried out in a way to minimise risk of contamination of the medicinal product and irradiation of the operators. Adequate shielding is mandatory.

The content of the kit before reconstitution is not radioactive. However, after sodium pertechnetate (^{99m}Tc) is added, adequate shielding of the final preparation must be maintained.

The administration of radiopharmaceuticals creates risks for other persons from external radiation or contamination from spills of urine, vomiting, etc. Radiation protection precautions in accordance with national regulations must therefore be taken.

Any unused product or waste material should be disposed of in accordance with local requirements for radioactive materials.

7 MARKETING AUTHORISATION HOLDER

Curium Netherlands B.V.
Westerduinweg 3
1755 LE Petten
The Netherlands

8 MARKETING AUTHORISATION NUMBER

PA0690/015/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 22 January 1999

Date of last renewal: 22 January 2009

10 DATE OF REVISION OF THE TEXT

August 2024

11 DOSIMETRY

Technetium (^{99m}Tc) is produced by means of a (^{99}Mo/^{99m}Tc) generator and decays with the emission of gamma radiation with a mean energy of 140 keV and a half-life of 6.01 hours to (^{99}Tc) technetium, which, in view of its long half-life of 2.13 x 10^5 years, can be regarded as quasi stable.

The data listed below are from ICRP 128 and are calculated according to the following assumptions:

- **Intravenous administration** of technetium (^{99m}Tc) pentetate gives rise to an initial distribution in the extracellular fluid. Following this initial distribution phase, the substance is excreted exclusively by the renal system. In case of normal renal function, total body retention is described by a bi-exponential function with component half-times of 100 min (0.99) and 7 days (0.01). The fraction excreted by the kidneys is 1.0 (1.0), and the renal transit time is 5 min. In case of abnormal renal function, it is assumed that the retention half-time of the major component is 1000 min, and the renal transit time is increased to 20 min.

According to the provisions of the International Commission of Radiological Protection (ICRP 128), the radiation doses absorbed by the patient after intravenous injection are the following:

	Absorbed dose per unit activity administered (mGy/MBq)				
Normal renal function					
Organ	**Adult**	**15 years**	**10 years**	**5 years**	**1 year**
Adrenals	0.0014	0.0018	0.0027	0.004	0.0072
Bone surfaces	0.0024	0.0029	0.0043	0.0061	0.010
Brain	0.00086	0.0011	0.0017	0.0028	0.0049
Breast	0.00072	0.00092	0.0013	0.0022	0.0041
Gallbladder	0.0015	0.0021	0.0038	0.005	0.0061
Gastrointestinal tract					
Stomach wall	0.0013	0.0017	0.0028	0.0040	0.0068
Small intestine wall	0.0025	0.0031	0.0049	0.0070	0.010
Colon wall	0.0031	0.0039	0.0060	0.0081	0.011
Upper large intestine wall	0.0021	0.0028	0.0043	0.0065	0.0092
Lower large intestine wall	0.0043	0.0054	0.0082	0.010	0.013
Heart wall	0.0012	0.0015	0.0022	0.0033	0.0059
Kidneys	0.0044	0.0053	0.0075	0.011	0.018
Liver	0.0012	0.0016	0.0025	0.0038	0.0064
Lungs	0.001	0.0013	0.002	0.003	0.0055
Muscles	0.0016	0.002	0.003	0.0043	0.0068
Ovaries	0.0042	0.0053	0.0077	0.01	0.013
Pancreas	0.0014	0.0018	0.0028	0.0043	0.0074
Red marrow	0.0015	0.0018	0.0027	0.0037	0.0057
Skin	0.00087	0.001	0.0017	0.0026	0.0044
Spleen	0.0013	0.0016	0.0026	0.0039	0.0068
Testes	0.0029	0.004	0.0068	0.0094	0.013
Thymus	0.001	0.0013	0.0019	0.0030	0.0054
Thyroid	0.001	0.0013	0.0021	0.0033	0.006
Urinary bladder wall	0.062	0.078	0.11	0.15	0.17
Uterus	0.0079	0.0096	0.015	0.018	0.022
Remaining organs	0.0017	0.0021	0.0030	0.0042	0.0066
Effective dose (mSv/MBq)					
	0.0049	0.0063	0.0094	0.012	0.016

The effective dose resulting from the administration of a maximal recommended activity of 740 MBq for an adult weighing 70 kg is about 3.6 mSv.
For an administered activity of 740 MBq the typical radiation dose to the target organ (kidneys) is 3.3 mGy and the typical radiation dose to the critical organ (urinary bladder wall) is 46 mGy.

	Absorbed dose per unit activity administered (mGy/MBq)				
Abnormal renal function					
Organ	**Adult**	**15 years**	**10 years**	**5 years**	**1 year**
Adrenals	0.0041	0.0051	0.0076	0.011	0.021
Bone surfaces	0.006	0.0071	0.011	0.015	0.028
Brain	0.0028	0.0035	0.0057	0.0091	0.016

Breast	0.0023	0.003	0.0042	0.0068	0.013
Gallbladder wall	0.0042	0.0057	0.0092	0.013	0.016
Gastrointestinal tract					
Stomach wall	0.0038	0.005	0.0079	0.011	0.019
Small intestine wall	0.0045	0.0056	0.0085	0.013	0.022
Colon wall	0.0045	0.0058	0.0087	0.013	0.022
Upper large intestine wall	0.0043	0.0056	0.0081	0.013	0.021
Lower large intestine wall	0.0049	0.0061	0.0095	0.013	0.023
Heart wall	0.0037	0.0047	0.007	0.01	0.018
Kidneys	0.0077	0.0092	0.013	0.019	0.032
Liver	0.0037	0.0046	0.0071	0.011	0.019
Lungs	0.0033	0.0042	0.0062	0.0095	0.017
Muscles	0.0032	0.004	0.0061	0.0091	0.017
Ovaries	0.005	0.0062	0.0092	0.014	0.023
Pancreas	0.0043	0.0053	0.008	0.012	0.021
Red marrow	0.0034	0.0042	0.0064	0.0093	0.016
Skin	0.0022	0.0026	0.0042	0.0067	0.012
Spleen	0.0038	0.0047	0.0073	0.011	0.019
Testes	0.0035	0.0045	0.0069	0.01	0.018
Thymus	0.0033	0.0042	0.0062	0.0096	0.017
Thyroid	0.0034	0.0042	0.0067	0.011	0.019
Urinary bladder wall	0.021	0.027	0.039	0.05	0.066
Uterus	0.0061	0.0074	0.011	0.016	0.025
Remaining organs	0.0033	0.0041	0.0063	0.0097	0.017
Effective dose (mSv/MBq)					
	0.0046	0.0058	0.0087	0.013	0.021

The physical half-life of ^{99m}Tc is 6.01 h.
The urinary bladder wall contributes up to 57% of the effective dose.

The data listed below are from ICRP 53 and are calculated according to the following assumptions:

- **Inhalation of technetium (^{99m}Tc) pentetate**

Inhalation of aerosol consisting of particles smaller than 2 - 3 micrometers in diameter results in deposition mainly in the alveoli. Particles are rapidly cleared from the lungs via the blood stream. The biological half-life of technetium (^{99m}Tc) pentetate in the lungs is 60-80 minutes in normal non-smokers; it is shortened in smokers and in most patients with lung disease. A value of 60 min is adopted below. Substance reaching the blood is eliminated according to the model for intravenously administered technetium (^{99m}Tc) pentetate.

According to ICRP 53 the radiation doses given to a man on administration by aerosol technetium (^{99m}Tc) pentetate are:

	Absorbed dose per unit activity administered (mGy/MBq)				
Organ	**Adult**	**15 years**	**10 years**	**5 years**	**1 year**
Adrenals	0.0021	0.0029	0.0044	0.0067	0.012
Bladder wall	0.047	0.058	0.084	0.12	0.23
Bone surfaces	0.0019	0.0024	0.0035	0.0053	0.0098
Breast	0.0019	0.0019	0.0033	0.0048	0.0078
Gastrointestinal tract					
Stomach wall	0.0017	0.0022	0.0035	0.0051	0.0089
Small intestine wall	0.0021	0.0026	0.0041	0.0063	0.011
Upper large intestine wall	0.0019	0.0024	0.0038	0.0061	0.01
Lower large intestine wall	0.0032	0.0042	0.0063	0.0088	0.015
Kidneys	0.0041	0.0051	0.0072	0.011	0.019
Liver	0.0019	0.0025	0.0037	0.0055	0.0097
Lungs	0.017	0.026	0.036	0.054	0.1

Ovaries	0.0033	0.0041	0.0061	0.0089	0.015
Pancreas	0.0021	0.0026	0.004	0.0061	0.011
Red marrow	0.0027	0.0034	0.0047	0.0062	0.0096
Spleen	0.0019	0.0024	0.0036	0.0056	0.0099
Testes	0.0021	0.0031	0.0052	0.0079	0.015
Thyroid	0.00099	0.0017	0.0027	0.0044	0.0078
Uterus	0.0059	0.0072	0.011	0.016	0.027
Other tissues	0.0018	0.0022	0.0032	0.0049	0.0086
Effective dose equivalent (mSv/MSq)					
	0.007	0.0091	0.013	0.02	0.036

The effective dose equivalent resulting from the inhalation of a maximal recommended activity of 100 MBq for an adult weighing 70 kg is about 0.7 mSv.
For an inhalated activity of 100 MBq the typical radiation dose to the target organ (lungs) is 1.7 mGy and the typical radiation dose to the critical organ (urinary bladder wall) is 4.7 mGy.

The data listed below are from ICRP 128 and are calculated according to the following assumptions:

- **Oral administration of technetium (^{99m}Tc) pentetate**

Technetium (^{99m}Tc) pentetate is considered as non-absorbable marker in studies of the gastrointestinal tract. The gastric residence time is fixed to 33 min for fluids.

The radiation doses given to a man on oral administration of technetium(^{99m}Tc) pentetate are the following:

	Absorbed dose per unit activity administered (mGy/MBq)				
Oral administration of fluids					
Organ	**Adult**	**15 years**	**10 years**	**5 years**	**1 year**
Adrenals	0.0025	0.0033	0.0055	0.0089	0.015
Bone surfaces	0.0042	0.0052	0.0074	0.011	0.021
Brain	0.0000018	0.0000034	0.000012	0.00004	0.0001
Breast	0.00028	0.00042	0.00094	0.002	0.0038
Gallbladder	0.014	0.018	0.03	0.043	0.071
Gastrointestinal tract					
Stomach wall	0.022	0.029	0.041	0.066	0.12
Small intestine wall	0.06	0.076	0.12	0.19	0.35
Colon wall	0.1	0.13	0.22	0.35	0.66
Upper large intestine wall	0.12	0.15	0.25	0.4	0.75
Lower large intestine wall	0.083	0.11	0.18	0.29	0.54
Heart wall	0.001	0.0014	0.0025	0.0043	0.0086
Kidneys	0.0055	0.0067	0.01	0.015	0.023
Liver	0.0037	0.0048	0.0093	0.015	0.027
Lungs	0.00057	0.00091	0.0016	0.0029	0.0057
Muscles	0.0032	0.004	0.006	0.009	0.015
Oesophagus	0.00019	0.0003	0.0005	0.0012	0.0026
Ovaries	0.025	0.032	0.048	0.068	0.11
Pancreas	0.0059	0.0079	0.012	0.018	0.031
Red marrow	0.0047	0.0057	0.0075	0.0092	0.011
Skin	0.00093	0.0011	0.0017	0.0029	0.0054
Spleen	0.004	0.005	0.0078	0.012	0.02
Testes	0.0013	0.002	0.0038	0.0065	0.012
Thymus	0.00019	0.0003	0.0005	0.0012	0.0026
Thyroid	0.00002	0.000048	0.00015	0.0003	0.0012
Urinary bladder wall	0.0069	0.0091	0.014	0.022	0.035
Uterus	0.016	0.02	0.031	0.047	0.076

Remaining organs	0.0052	0.0072	0.011	0.02	0.03
Effective dose (mSv/MBq)					
	0.019	0.025	0.039	0.062	0.11

The effective dose resulting from the oral administration of a maximal recommended activity of 20 MBq for an adult weighing 70 kg is about 0.38 mSv.

For an administered activity of 20 MBq the typical radiation dose to the target organ (stomach) is 0.44 mGy and the typical radiation doses to the critical organs (upper large intestine and lower large intestine) are 2.4 and 1.66 mGy, respectively.

12 INSTRUCTIONS FOR PREPARATION OF RADIOPHARMACEUTICALS

Withdrawals should be performed under aseptic conditions. The vials must not be opened, the solution should be withdrawn via the stopper using a single dose syringe fitted with suitable protective shielding and a disposable sterile needle or using an authorised automated application system.
If the integrity of this vial is compromised, the product should not be used

Method of preparation
Inject the required amount of Sodium Pertechnetate(^{99m}Tc) Injection (Fission or Non-Fission), up to a maximum of 11.1 GBq (300 mCi), in a volume of 2-10 ml to a vial of TechneScan DTPA. Mix until the content of the vial is completely dissolved. After an incubation time of 15-30 minutes at 15°C - 25°C, the product is ready for administration to a patient.

Properties of the labelled compound:
Clear to slightly opalescent, colourless aqueous solution
pH : 4.0-5.0
Labelling yield : ≥ 95%

Quality control instructions
Quality control is performed by thin layer chromatography (TLC) on fiberglass sheets coated with silica gel.
a Dissolve 5 to 10 microliters in 0.9% m/V sodium chloride solution R; the technetium pentetate complex and pertechnetate ion migrate near the solvent front, impurities in colloidal form remain at the start.
b Dissolve 5 to 10 microliters in methyl ethyl ketone R; pertechnetate ion migrates near the solvent front, technetium pentetate complex and impurities in colloidal form remain at the start. For particulars consult the European Pharmacopoeia (Monograph 642).