RADPHARM **L4.2**
SCIENTIFIC

DMSA Radpharm
Kit for the Preparation of Technetium[^{99m}Tc] Succimer Injection for Renal Imaging

Product Data **AUST R 14326**

DESCRIPTION
This Kit consists of sterile, pyrogen free lyophilised ingredients which need reconstitution with sodium pertechnetate[^{99m}Tc] injection to produce a technetium[^{99m}Tc] succimer complex suitable for renal imaging.
The precise structure of the technetium[^{99m}Tc] succimer complex is not known at this time.
Technetium[^{99m}Tc] succimer is a diagnostic pharmaceutical administered by intravenous injection.

CONTENTS AND PRESENTATION
DMSA Radpharm is supplied as a carton of 5 sterile, pyrogen free, vacuum sealed multidose 8 mL vials.
Each vial contains 1 mg succimer (*meso*-2,3-dimercaptosuccinic acid), 0.4 mg stannous chloride anhydrous, 0.7 mg ascorbic acid and 50.0 mg inositol as a lyophilised powder.
The product contains no preservatives.

PHYSICAL CHARACTERISTICS OF TECHNETIUM-99m
Technetium-99m with a physical half life of 6 hours decays by isomeric transition to technetium-99. Photons associated with this transition that are useful for detection and imaging studies are listed in Table 1.

Table 1. Principal Radiation Emission Data

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

Reference: D A Weber et al. "MIRD: Radionuclide and decay schemes", The Society of Nuclear Medicine Inc. New York, 1989.

Table 2. Physical Decay Chart for Technetium-99m

Hours	Fraction Remaining	Hours	Fraction Remaining
0	1.000	7	0.445
1	0.891	8	0.397
2	0.794	9	0.354
3	0.707	10	0.315
4	0.630	11	0.281
5	0.561	12	0.250
6	0.500		

EXTERNAL RADIATION
The specific gamma ray constant for technetium-99m is 0.19 mGy/MBq-h at 1 cm. The first half value thickness of lead (Pb) for technetium-99m is 0.2 mm. Attenuation by lead is given in Table 3.

Table 3. Radiation Attenuation by Lead Shielding

Shield Thickness mm Pb	Coefficient of Attenuation
0.95	0.1
1.8	0.01
2.7	0.001
3.6	0.0001

PHARMACOLOGY
Technetium[^{99m}Tc] succimer exhibits insignificant glomerular filtration but is tubularly secreted with tubular binding in the renal cortex. It binds to receptors in microsomes of proximal tubular cells. Renal clearance is slow (10% in 1st hour) with 15% uptake in liver and 40 to 50% uptake in kidneys at 3 hours. Plasma clearance is triexponential with half-lives of 40 minutes, 2.1 hours and 6 days.

INDICATIONS
Technetium[^{99m}Tc] succimer may be used as a static renal imaging pharmaceutical and is particularly suited for evaluation of renal cortex, delineation of renal space occupying lesions, determination of intrarenal function distribution and identification of ectopic renal sites.

CONTRAINDICATIONS
None known.

PRECAUTIONS
General
Radiopharmaceuticals should be used only by physicians who are qualified by specific training in the safe use and handling of radionuclides.
Contents of the vial are intended only for use in the preparation of technetium[^{99m}Tc] succimer.
The radioactivity of the dose should be checked with a suitable instrument immediately prior to administration.
Disposal of all radioactive wastes should be carried out in accordance with the NH & MRC "Code of Practice for the Disposal of Radioactive Wastes by the User" (1985).
Use in Pregnancy
Technetium-99m radiopharmaceuticals should only be given to a pregnant woman if in the judgement of the treating physician the expected benefits outweigh the potential hazards.
Use during Lactation
Technetium-99m is excreted in human milk. Interruption to breast feeding is not essential after the administration of technetium[^{99m}Tc] succimer (a mother can be reassured by advising an interruption of 4hr). (Reference: L.K. Harding, A. Bossuyt, S. Pellet, C. Reiners, J.N. Talbot, "Recommendations for nuclear medicine physicians regarding breastfeeding mothers", *Eur.J.Nucl.Med.*, 1995, **22**, BP17).

ADVERSE REACTIONS
For each patient, exposure to ionising radiation must be justifiable on the basis of likely benefit. The activity administered must be such that the resulting dose is as low as reasonably achievable bearing in mind the need to obtain the intended diagnostic or therapeutic result.
Exposure to ionising radiation is linked with cancer induction and a potential for development of hereditary defects. For diagnostic nuclear medicine investigations the current evidence suggests that these adverse effects will occur with low frequency because of the low radiation doses incurred.
For most diagnostic investigations using a nuclear medicine procedure the radiation dose delivered (EDE) is less than 20 mSv. Higher doses may be justified in some clinical circumstances.
Occasional “allergic reactions” have been reported in literature although to date these have been inadequately described.

DOSAGE AND ADMINISTRATION
Recommended intravenous dose for the normal adult is 60-80 MBq.
Recommended normal child maximum dose is 30 MBq.
Radiation Dosimetry

Table 4. Estimated Absorbed Dose from Intravenous Administration of Technetium[^{99m}Tc] Succimer

Organ	**mGy/MBq**				
	Adult	15 year	10 year	5 year	1 year
Adrenals	1.3E-02	1.6E-02	2.4E-02	3.5E-02	6.0E-02
Bladder wall	1.9E-02	2.4E-02	3.5E-02	5.1E-02	9.4E-02
Bone surfaces	3.5E-03	4.3E-03	6.4E-03	9.9E-03	1.2E-02
Breast	1.8E-03	1.8E-03	2.8E-03	4.5E-03	8.4E-03
GI-tract					
Stomach wall	5.5E-03	6.3E-03	9.8E-03	1.3E-02	2.0E-02
Small intestine	5.2E-03	6.4E-03	1.0E-02	1.5E-02	2.5E-02
ULI wall	5.1E-03	6.3E-03	9.6E-03	1.4E-02	2.3E-02
LLI wall	3.2E-03	4.2E-03	6.7E-03	1.0E-02	1.8E-02
Kidneys	1.7E-01	2.1E-01	2.9E-01	4.2E-01	7.3E-01
Liver	9.7E-03	1.2E-02	1.8E-02	2.5E-02	4.1E-02
Lungs	2.5E-03	3.5E-03	5.2E-03	8.0E-03	1.4E-02
Ovaries	3.7E-03	4.6E-03	7.2E-03	1.1E-02	2.0E-02
Pancreas	9.0E-03	1.1E-02	1.6E-02	2.3E-02	3.7E-02
Red marrow	6.3E-03	7.5E-03	1.0E-02	1.4E-02	2.0E-02
Spleen	1.3E-02	1.7E-02	2.6E-02	3.8E-02	6.1E-02
Testes	1.8E-03	2.4E-03	3.9E-03	6.2E-03	1.2E-02
Thyroid	1.1E-03	1.9E-03	3.1E-03	5.1E-03	9.2E-03
Uterus	4.6E-03	5.5E-03	8.9E-03	1.3E-02	2.3E-02
Other tissue	3.0E-03	3.6E-03	5.2E-03	8.0E-03	1.4E-02
Effective Doses (mSv/MBq):	8.7E-03	1.1E-02	1.6E-02	2.3E-02	4.0E-02

Reference for Estimated Absorbed Dose: ICRP Publication 53, Radiation Dose To Patients from Radiopharmaceuticals (1987).
The Effective Doses have been calculated using the weighting factors given in ICRP Publication 60, 1990 Recommendations of the International Commission on Radiological Protection (1991).

Procedure
NOTE: If there is no vacuum, discard vial and do not deliver the sodium pertechnetate[^{99m}Tc] injection.

1. Place DMSA Radpharm vial in shielding container.
2. Draw a suitable volume (2-5 mL) of sodium pertechnetate[^{99m}Tc] injection eluted from a technetium-99m generator, (up to 1.5 GBq), and inject into the DMSA Radpharm vial. Mix by slow inversion for 20 seconds and leave standing at room temperature for 10 minutes before use.
3. Determine the radioactivity per millilitre, label the container and calculate the patient dose.
4. This technetium[^{99m}Tc] succimer solution is stable at room temperature
5. and may be used up to 6 hours after preparation.

Stability after Reconstitution with Technetium-99m
After reconstitution of DMSA Radpharm with sodium pertechnetate[^{99m}Tc] injection, (up to 1.5 GBq), the technetium[^{99m}Tc] succimer complex is stable at room temperature for 6 hours.

STORAGE AND EXPIRY
The DMSA Radpharm vials must be stored at 2^{o}C to 8^{o}C (Refrigerate. Do not freeze.)
Expiry is 12 months from the date of manufacture. The expiry date is stated on the vial and carton.

MANUFACTURER
This product is manufactured by Radpharm Scientific, 54 - 59 Oatley Court, Belconnen, 2617 ACT Australia.

Approved by TGA 20 September 2006

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