

DMSA Radpharm

Kit for the Preparation of Technetium[99mTc] 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[99mTc] injection to produce a technetium[99mTc] succimer complex suitable for renal imaging

The precise structure of the technetium[99mTc] succimer complex is not known at this time.

Technetium[99mTc] 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 5 mL vials.

Each vial contains 1 mg succimer (meso-2,3-dimercaptosuccinic acid), 0.4 mg tin(II) chloride anhydrous, 0.7 mg ascorbic acid and 50.0 mg inositol as a lyophilised powder.

The product contains no preservatives.

PPHARMACOLOGY

Technetium[99mTc] 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[99mTc] 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.

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.

Any suspected adverse reaction should be reported to Adverse Drug Reactions Advisory Committee (ADRAC) TGA, PO Box 100 WODEN ACT 2606.

Tel: 06 289 8670 Fax: 06 289 7694.

DOSAGE AND ADMINISTRATION

Recommended intravenous dose for the normal adult is 60-80 MBq.

Recommended normal child maximum dose is 30 MBq.

Procedure

NOTE: If there is no vacuum, discard vial and do not deliver the sodium pertechnetate[99mTc] injection.

1. Place DMSA Radpharm vial in shielding container.
2. Draw a suitable volume (2-5 mL) of sodium pertechnetate[99mTc] 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[99mTc] succimer solution is stable at room temperature and may be used up to 3 hours after preparation.

Stability after Reconstitution with Technetium-99m

After reconstitution of DMSA Radpharm with sodium pertechnetate[99mTc] injection, (up to 1.5 GBq), the technetium[99mTc] succimer complex is stable at room temperature for 3 hours.

STORAGE AND EXPIRY

The DMSA Radpharm vials must be stored at 2 to 8oC (Refrigerate. Do not freeze.)

Expiry is 9 months from the date of manufacture. The expiry date is stated on the vial and carton.

MANUFACTURER

This product is manufactured by Radpharm Scientific, Unit 3 Oatley Lane Belconnen, 2617 ACT Australia