

DTPA Radpharm

## **Kit for the Preparation of Technetium[99mTc] Pentetate Injection for Renal Imaging**

**Product Data AUST R 14327**

### **DESCRIPTION**

This Kit consists of sterile, pyrogen free lyophilised ingredients which need reconstitution with sodium pertechnetate[99mTc] injection to produce a technetium[99mTc] pentetate complex suitable for renal imaging.

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

Technetium[99mTc] pentetate is a diagnostic pharmaceutical administered by intravenous injection.

### **CONTENTS AND PRESENTATION**

DTPA Radpharm is supplied as a carton of 5 sterile, pyrogen free, vacuum sealed 5 mL vials.

Each vial contains 5 mg pentetic acid and 1 mg tin(II) chloride anhydrous as a lyophilised powder.

The product contains no preservatives.

### **PHARMACOLOGY**

Following intravenous administration of technetium[99mTc] pentetate to normal patients the radiopharmaceutical is rapidly distributed in the extracellular fluid space then cleared from the body through the kidneys. There is minimal binding to renal parenchyma and it clears the kidneys by glomerular filtration.

The images taken in the first minutes demonstrate kidney vascular pool and subsequent images represent technetium[99mTc] pentetate in both the collecting system and the renal pelvis.

### **INDICATIONS**

Technetium[99mTc] pentetate may be used as a renal perfusion imaging pharmaceutical.

### **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/s are intended only for use in the preparation of technetium[99mTc] pentetate.

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 necessary after the administration of technetium[99mTc] pentetate for a period less than 12h.

(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.

In isolated cases the following adverse reactions have been reported: flushing, dizziness, dyspnoea, itch, urticaria and hypotension.

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 200 MBq.

### Procedure

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

1. Place DTPA Radpharm vial in a shielding container.
2. Draw a suitable volume (1 to 4 mL) of sodium pertechnetate[99mTc] injection eluted from a technetium-99m generator (1 to 3 GBq) and inject into the DTPA Radpharm vial. Mix by inversion for 30 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. The technetium[99mTc] pentetate solution is stable at room temperature and may be used up to 5 hours after preparation.

### Stability after Reconstitution with Technetium-99m

After reconstitution of DTPA Radpharm with sodium pertechnetate[99mTc] injection, (1 to 3 GBq), the technetium[99mTc] pentetate complex is stable at room temperature for 5 hours.

## **STORAGE AND EXPIRY**

The DTPA Radpharm vials must be stored below 25°C.

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, Unit 3 Oatley Lane Belconnen, 2617 ACT Australia