

COLLOID Radpharm

## **Kit for the Preparation of Technetium[99mTc] Calcium Phytate Colloid Injection for Liver/Spleen Imaging**

**Product Data AUST R 14332**

### **DESCRIPTION**

The agent comprises sterile, pyrogen free lyophilised ingredients which need reconstitution with sodium pertechnetate[99mTc] injection and addition of Calcium Radpharm to produce a technetium[99mTc] calcium phytate colloid suitable for liver/spleen imaging. The precise structure of the technetium[99mTc] calcium phytate colloid is not known at this time.

Technetium[99mTc] calcium phytate colloid is a diagnostic pharmaceutical administered by intravenous injection.

### **CONTENTS AND PRESENTATION**

This is a composite kit consisting of a PHYTATE Radpharm vial (lyophilised) and a CALCIUM Radpharm vial (solution).

PHYTATE Radpharm is supplied as a carton of 5 sterile, pyrogen free, vacuum sealed 10 mL vials containing 23.4 mg phytic acid and 1.0 mg tin(II) chloride anhydrous as a lyophilised powder. CALCIUM Radpharm is supplied as a carton of 5 sterile, pyrogen free 5 mL vials containing a 1.2 mL solution of 5 mg/mL potassium hydrogen phthalate and 13.5 mg/mL calcium chloride in Water for Injection BP.

The product contains no preservatives.

### **PHARMACOLOGY**

The liver is an organ of the reticuloendothelial system and it consists of two main cell types. The parenchymal (polyclonal) cells perform the metabolic functions and account for 85% of the cell population. The reticuloendothelial (Kupfer) cells, which are also present in the spleen and bone marrow, phagocytose foreign particles of colloidal dimensions. Radioactive colloids are rapidly removed from the circulation by these cells. Any lesion that displaces normal liver tissue will appear as a photopenic site as it does not take up the radiocolloid.

### **INDICATIONS**

Technetium[99mTc] calcium phytate colloid may be used as a liver/spleen imaging pharmaceutical for determining liver size and shape, and for investigation of a malignancy, infections, trauma and cirrhosis.

### **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.

Adverse reactions have not been reported for this product, to date.

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 120-160 MBq.

### **Procedure**

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

1. Place PHYTATE Radpharm vial in a shielding container.
2. In a 10 mL syringe, draw up the required amount of sodium pertechnetate[99mTc] injection eluted from a technetium-99m generator, (up to 3 GBq), and make the volume to 10 mL with sodium chloride injection.
3. Inject the 10 mL of sodium pertechnetate[99mTc] injection to the PHYTATE Radpharm vial and mix for 10 seconds.
4. Draw up 0.25 mL of CALCIUM Radpharm and add to the technetium[99mTc] PHYTATE Radpharm vial. Mix for 20 seconds and leave standing at room temperature for 10 minutes before use.
5. Determine the radioactivity per millilitre, label the container and calculate the patient dose.
6. This technetium[99mTc] calcium phytate colloid is stable at room temperature and may be used up to 6 hours after preparation.

Splenic Trauma

Spleen uptake may be increased by changing the volume of CALCIUM Radpharm in Step 4 from 0.25 mL to 0.5 mL.

Although the method of choice for optimum spleen imaging is to heat damage technetium[99mTc] labelled autologous red blood cells.

Stability after Reconstitution with Technetium-99m

After reconstitution of PHYTATE Radpharm with sodium pertechnetate[99mTc] injection, (up to 3 GBq) and addition of CALCIUM Radpharm, the resultant technetium[99mTc] calcium phytate colloid is stable at room temperature for 6 hours.

## **STORAGE AND EXPIRY**

COLLOID Radpharm 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.