

PYP Radpharm

Kit for the Preparation of Tin Pyrophosphate Injection for Blood Pool Imaging

Product Data AUST R 14328

DESCRIPTION

This Kit consists of sterile, pyrogen free lyophilised ingredients which need reconstitution with sodium chloride injection.

Reconstituted PYP Radpharm is a diagnostic pharmaceutical administered by intravenous injection and is suitable for blood pool imaging.

CONTENTS AND PRESENTATION

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

Each vial contains 30 mg sodium pyrophosphate and 9 mg tin(II) chloride anhydrous (5.6 mg stannous ion) as a lyophilised powder.

The product contains no preservatives.

PHARMACOLOGY

Following intravenous administration of PYP Radpharm to the blood, stannous ions in the pharmaceutical pre-tint the erythrocytes. Sodium pertechnetate[^{99m}Tc] injection is then administered to the blood, the technetium-99m passively diffuses into the erythrocyte where it is reduced by the stannous ion enabling technetium-99m radiolabelling of the cell. Stannous reduced technetium-99m preferentially bonds to the beta globin chain of the erythrocyte haemoglobin.

INDICATIONS

Technetium[^{99m}Tc] labelled erythrocytes are used in the non invasive evaluation of cardiac ventricular function and heart wall motion.

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 after the intravenous administration of both the unlabelled and the technetium [99mTc] complexes have been reported in isolated cases (1-5 per 100,000 uses). The following effects have been described: flush, headache, vasodilation, nausea, dizziness, swelling of the arm, erythema and itching at the injection site, diaphoresis and tinnitus, urticaria, generalised pruritus. Cardiac arrhythmia, facial oedema and coma have been reported.

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

Procedure

Reconstitution of PYP Radpharm:

NOTE: If there is no vacuum, discard the vial and do not deliver the sodium chloride injection.

1. Draw 5 mL of sodium chloride injection and deliver to the PYP Radpharm vial.
2. Mix the contents of the vial for 20 seconds and leave standing at room temperature for 5 minutes.
3. The PYP Radpharm solution is stable at room temperature for 5 hours.
4. This product with 1.1 mg/mL stannous ion per vial supplies sufficient tin for 4 to 6 studies.

Red Cell Tinning.

1. Administer intravenously between 0.8 and 1.0 mL of the saline reconstituted PYP Radpharm and allow 15 to 20 minutes for ideal red blood cell tinning.

2a) 'In-Vivo'

Administer intravenously, sodium pertechnetate[99mTc] injection eluted from a technetium-99m generator, (500 - 700 MBq).

OR

2b) 'Modified "In-Vivo"'

Draw blood into a syringe containing heparin sodium and sodium pertechnetate[^{99m}Tc] injection, (500 - 700 MBq), mix for 5-10 minutes before reinjection.

Stability after Reconstitution with sodium chloride injection

After reconstitution of PYP Radpharm with sodium chloride injection the pharmaceutical is stable at room temperature for 5 hours.

STORAGE AND EXPIRY

The PYP 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 ACT Australia.