

MDP Radpharm

Kit for the Preparation of Technetium[99mTc] Medronate Injection for Bone Scanning

Product Data AUST R 14330

DESCRIPTION

This Kit consists of sterile, pyrogen free lyophilised ingredients which need reconstitution with sodium pertechnetate[99mTc] injection to produce a technetium[99mTc] medronate complex suitable for bone scanning. The precise structure of the technetium[99mTc] medronate complex is not known at this time.

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

CONTENTS AND PRESENTATION

MDP Radpharm is supplied as a carton of 10 sterile, pyrogen free, vacuum sealed multidose 10 mL vials.

Each vial contains 10 mg medronic acid, 1 mg tin(II) chloride anhydrous and 1 mg ascorbic acid as a lyophilised powder. The product contains no preservatives.

PHARMACOLOGY

After intravenous administration of technetium[99mTc] medronate, skeletal uptake appears to be related to bone metabolic activity and skeletal blood flow. Technetium[99mTc] medronate demonstrates specific affinity for areas of altered osteogenesis.

Localised areas of decreased bone uptake may occur after therapeutic external irradiation.

Blood clearance of technetium[99mTc] medronate is multiexponential with an initial fall in blood concentration with half-time($t_{1/2} = 3.5$ minutes), followed by medium ($t_{1/2} = 27$ minutes) and slow ($t_{1/2} = 144$ minutes). The initial blood clearance represents the relatively rapid movement of technetium[99mTc] medronate from the vascular compartments to other compartments. The other clearance rates are functions of bone uptake and renal clearance and protein binding of tracer. Blood levels fall to 3-5% of the injected dose by 3 hours post injection.

INDICATIONS

Technetium[99mTc] medronate may be used as a skeletal imaging pharmaceutical.

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.

Occasionally (approximately 0.5 out of 100,000 investigations), hypersensitivity reactions may occur following intravenous administration of technetium [99mTc] medronate. Cases of local rash or generalised rash with itching and dermal irritation have been reported. Onset of the reaction is commonly several hours post-injection and it may last up to 48 hours. Treatment with a non-selective histamine H1 antagonist is helpful.

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 740 MBq.

Procedure

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

1. Place MDP Radpharm vial in a shielding container.
2. Draw a suitable volume (2 to 8 mL) of sodium pertechnetate[99mTc] injection eluted from a technetium-99m generator (1 to 16 GBq), and inject into the MDP Radpharm vial. Mix by 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. The technetium[99mTc] medronate solution is stable at room temperature and may be used up to 8 hours after preparation.

NOTE: In order to reduce the radiation dose to the bladder and other organs, the patient should be encouraged to drink and void as frequently as possible

for a period of 4 to 6 hours after the administration of technetium[99mTc] medronate.

Stability after Reconstitution with Technetium-99m

After reconstitution of MDP Radpharm with sodium pertechnetate[99mTc] injection, (1 to 16GBq), the technetium[99mTc] medronate complex is stable at room temperature for 8 hours.

STORAGE AND EXPIRY

The MDP Radpharm vials must be stored at 20C to 80C (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, Unit 3 Oatley Lane Belconnen, 2617 ACT Australia.