Technescan™ HDP

Reliable bone scintigraphy

Bone scintigraphy with Technescan™ HDP gives you the advantages of a stabilized Technetium labelling kit combined with fast, reliable results.

Technescan™ HDP offers you:

- Gentisic acid ensures stability of the kit after labelling
- Greater retention found in bone versus soft tissue than with MDP
  - A better image quality observed than with MDP
  - One hour faster imaging possible with the same quality as with other diphosphonates
- Potential for more economic use of both the agent and imaging equipment
- Long shelf life after production (2 years)
- Storage of the unlabelled product at room temperature (<25°C)
  - Unique colour coded outer packaging and vials for added user friendliness and safety

Indications:

- Bone scintigraphy
- Areas of osteoblastic activity

*see back page for abbreviated prescribing information

References:

1) Data on file /Packing insert
3) Pauwels et al; A comparison between whole body scans made at two hours and three hours after intravenous injection of Tc-99m HDP as to image quality and lesion detectability. Clinical NuclMed, 1984; Vol9, No 2:75-78
INDICATIONS This medicinal product is for diagnostic use only. After reconstitution with Sodium Pertechnetate (99mTc) Injection the agent may be used for bone scintigraphy, where it delineates areas of altered osteogenesis.

POSOLOGY AND METHOD OF ADMINISTRATION

Adults The average activity administered by single intravenous injection is 500 MBq (300-700 MBq) in a 50 to 70 kg weighing adult. There is no special dosage regimen for the elderly patient. Other activities may be justifiable. Children The dose to be administered to a child should be a fraction of the adult dose calculated from the body weight. CONTRAINDICATIONS Hypersensitivity to the active substance or to any of the excipients. SPECIAL WARNINGS AND SPECIAL PRECAUTIONS FOR USE In infants and children particular attention should be paid to the relatively high radiation exposure of the epiphyses in growing bone. To reduce the radiation exposure to the bladder wall, sufficient hydration of the patient and frequent voiding is recommended. To avoid accumulation of tracer in the musculature it is advised that strenuous exercise is discouraged immediately after injection until satisfactory bone imaging has been effected. Inadvertent or accidental subcutaneous administration of technetium (99mTc) oxidronate should be avoided as perivascular inflammation has been described. Excipients: The injection contains sodium. This needs to be taken into considerations for patients on a controlled sodium diet. UNDESIRABLE EFFECTS In very rare cases (less than 0.001 %), hypersensitivity reactions of the anaphylactoid type have been reported after the use of technetium (99mTc) oxidronate injection with the most frequent symptoms being skin reactions, nausea, hypotension and pain. The onset of symptoms may be delayed 4 to 24 hours post injection. Extravasation of the radioactive material may lead to local reactions at the injection site including thrombophlebitis. 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 radiation dose is as low as reasonably achievable bearing in mind the need to obtain the intended diagnostic 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 (effective dose equivalent, EDE) is less than 20 mSv. Higher doses may be justified in some clinical circumstances. MARKETING AUTHORISATION HOLDER Mallinckrodt Medical B.V. Westerdierweg 3 1755 LE Petten The Nederlands. DATE OF REVISION OF THE TEXT 17. December 2008

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