Technescan™ PYP

- Multi dose vials may be used for in vivo, in vitro and semi-vitro Technetium red blood cell labeling procedures.  
- In vivo labeling of red blood cells was found to result in a mean RBC labeling of greater than 95% during the first hour after pertechnetate injection.
TRADENAME OF THE MEDICINAL PRODUCT: Technescan™ PYP

QUALITATIVE AND QUANTITATIVE COMPOSITION: Sodium pyrophosphate 11.93 mg.

INDICATIONS:

POSOLOGY AND METHOD OF ADMINISTRATION:
Administration is by intravenous injection. Red blood cell (RBC) labelling methods:
The stannous pyrophosphate lyophilisate (non radioactive substance) is first reconstituted with isotonic sodium chloride solution for injection. In-vivo method: Injection of the reconstituted solution of the stannous pyrophosphate complex and consecutive injection of sodium 99mTc pertechnetate 30 minutes later. In-vitro method: Sampling of 10 ml of the patient's blood. In-vitro incubation of the reconstituted solution with the sampled whole blood or separated red blood cells, followed 30 minutes by the addition of sodium 99mTc pertechnetate and reinjection of the labelled red blood cells. Modified in-vivo method (in-vivo/in-vitro): Injection of the reconstituted solution of the stannous pyrophosphate complex for in-vivo “stannous loading” of RBC. In-vitro RBC labelling with sodium 99mTc pertechnetate after withdrawal of a blood sample. Reinjection of the labelled red blood cells. Denatured red blood cell labelling In-vitro red blood cell labelling followed by denaturation of the erythrocytes e.g. heating 49-50°C for 25 minutes. Reinjection of the labelled denaturated red blood cells. Posology A Blood pool scintigraphy. The average activity administered by single injection after in-vivo or in-vitro labelling is 890 MBq (740-925 MBq). B Determination of blood volume. The average activity administered by single injection after in-vitro labelling is 3 MBq (1-5 MBq). C Spleen scintigraphy. The average activity administered by single injection for in-vitro labelling of de naturated erythrocytes is 50 MBq (20-70 MBq). The optimal amount of nonradioactive stannous tin for preparation of red blood cells in-vivo or in-vitro is 0.05 μg to 1.25 μg per ml of the total blood volume of the patient (near 5000 ml in a man of 70 kg weight). Especially in cases of in-vitro labelling this dose of stannous tin should not be exceeded. Sodium 99mTc pertechnetate should be injected (in-vivo) or added to the incubation mixture (in-vitro) after 30 minutes. Scanning can be started immediately after injection of the tracer. Paediatric doses: The activity for children may be calculated from the recommended range of adult activity and adjusted according to body weight or surface area.

CONTRAINDICATIONS:
Hypersensitivity to the active substance(s) or to any of the excipients.

SPECIAL WARNINGS AND PRECAUTIONS FOR USE:
It is recommended that In vivo 99mTc RBC labelling be performed prior to administration of iodinated contrast media. Otherwise, labelling efficiency will be adversely affected. In infants and children, a particularly careful assessment must be made of the diagnostic value, necessity for and risks of the procedure.

INTERACTIONS WITH OTHER MEDICINAL PRODUCTS AND OTHER FORMS OF INTERACTIONS:
Reduction in red blood cell labelling yield has been reported with heparin, tin overload, aluminium, prazosin, methyldopa, hydralazine, digital related compounds, quinidine, -adrenergic blockers (e.g. propanolol) calcium channel blockers (e.g. verapamil, niledipine), nitrates (e.g. nitroglycerin), anthracycline antibiotic, iodinated contrast agents and Teflon catheter (the Sn ++ can react with the catheter).

UNDESIRABLE EFFECTS:
Adverse reactions after the intravenous administration of both the unlabelled and the 99mTc complexes have been reported in isolated cases (1-5 per 100,000 uses). Usually, these adverse events are mild to moderate and of short duration, although some have been described as serious. Side effects reported after the use of Technescan PYP were mostly intolerance reactions of the allergy type including e.g. dizziness and headache, nausea and vomiting, flushing, skin rashes, face oedema, or hypotension. Also vasovagal reactions, cardiac arrythmias, and local reactions at the injection site have been reported.

MARKETING AUTHORISATION HOLDER:
Mallinckrodt Medical B.V. Westerduinweg 3 1755 LE Petten The Netherlands.

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