

**PRESCRIBING INFORMATION MYOVIE™ (Kit for radiopharmaceutical preparation)**

Please refer to full national Summary of Product Characteristics (SPC) before prescribing.

Indications and approvals may vary in different countries. Further information available on request.

**PRESENTATION** Lyophilisate containing 230 micrograms tetrofosmin / vial, for reconstitution with Sodium Pertechnetate [<sup>99m</sup>Tc] injection Ph. Eur. to yield <sup>99m</sup>Tc-tetrofosmin injection.

**INDICATIONS** i) Myocardial perfusion agent for use as an adjunct in the diagnosis and localisation of myocardial ischaemia and/or infarction. In patients undergoing myocardial perfusion scintigraphy, ECG-gated SPECT can be used for assessment of left ventricular function (left ventricular ejection fraction and wall motion). ii) As an adjunct to the initial assessments in the characterisation of malignancy of suspected breast lesions where other tests are inconclusive.

**DOSAGE AND METHOD OF ADMINISTRATION** For diagnosis and localisation of myocardial ischaemia (using planar or SPECT techniques) and assessment of left ventricular function using ECG-gated SPECT, two intravenous injections are administered, one given at peak stress and one given at rest (in either order). When rest and stress injections are given on the same day, the activity administered for the second dose should result in a myocardial count rate at least three times greater than the residual activity of the first dose. The recommended activity for the first dose is 250-400MBq followed by 600-800MBq for the second dose at least 1 hour later. When rest and stress injections are given on different days, the recommended activity for each dose is 400-600MBq. For studies on larger individuals and for studies employing ECG-gated SPECT the use of activities at the higher end of these ranges is warranted. The total activity administered for the procedure whether performed on one or two days should be restricted to 1200MBq. As an adjunct in the diagnosis and localisation of myocardial infarction 250-400MBq is given at rest. Patients should fast overnight or have only a light meal on the morning of the procedure. Planar or SPECT imaging may be acquired between 15 minutes and 4 hours post-injection. For breast imaging an intravenous injection of 500-750MBq preferably in a foot vein or site other than the arm on the side of suspected breast lesions. Not recommended for use in children or adolescents.

**CONTRAINDICATIONS** Pregnancy. Hypersensitivity to tetrofosmin or any of the excipients.

**WARNINGS AND PRECAUTIONS** The possibility of hypersensitivity including anaphylactic/anaphylactoid reactions should always be considered. Advanced life support facilities should be readily available. Breast lesions less than 1cm in diameter may not all be detected. Efficacy in the identification of axillary lesions has not been proven. Activity administered must be such that radiation dose is as low as reasonably achievable. Myoview is not recommended for use in children or adolescents. An increased exposure in those with renal or hepatic impairment is possible. The patient should be well hydrated before the start of the examination and urged to void as often as possible during the first hours after the examination in order to reduce radiation. This medicinal product contains 15 – 29 mg sodium per reconstituted vial, equivalent to 0.7 – 1.4% of the WHO recommended maximum daily intake of 2 g sodium for an adult.

**INTERACTIONS** For cardiac use consider current medication when assessing images as drugs which influence myocardial function and/or blood flow (e.g. beta blockers, calcium antagonists, nitrates) can lead to false negative results in diagnosis of coronary artery disease.

**PREGNANCY AND LACTATION** Contraindicated in pregnancy. Information should be sought about pregnancy from women of child bearing potential. A woman who has missed a period should be assumed to be pregnant. If administration to a breast-feeding woman is necessary, breastfeeding should be interrupted for 3 to 6 hours and the expressed feeds discarded.

**UNDESIRABLE EFFECTS** Adverse drug reactions following administration of <sup>99m</sup>Tc-tetrofosmin are very rare (<0.01%).

The following have been reported: **Immune system disorders:** Not known: Hypersensitivity reactions, including anaphylactoid or anaphylactic reactions and anaphylactic or anaphylactoid shock. **Nervous system disorders:** Uncommon: Taste metallic, Rare: Disturbances of smell, Not known: Headache, dizziness. **Eye disorders:** Rare: Abnormal vision. **Cardiac disorders:** Not known: Tachycardia, chest pain. **Vascular disorders:** Uncommon: Flushing, Not known: Hypotension. **Respiratory, thoracic and mediastinal disorders:** Not known: Dyspnoea, bronchospasm, throat tightness, cough. **Gastrointestinal disorders:** Uncommon: Vomiting, Rare: Abdominal pain, nausea, burning mouth. **Skin and subcutaneous tissue disorder:** Rare: Rash, Not known: Urticaria, pruritus, erythema, angioedema. **General disorders and administration site conditions:** Uncommon: Feeling of warmth, Not known: Local swelling, face oedema, fever. **Investigations:** Not known: White blood cell count increased. Some reactions were delayed by several hours following product administration. Isolated cases of serious reactions have been reported, including anaphylactic reaction (less than 1 in 100,000), single case of severe allergic reaction. The major risk is due to radiation which can cause cancer and genetic changes, these effects are expected to occur with a low frequency.

**DOSIMETRY** The effective dose (ED) is 8.5mSv when the maximal recommended activity of 1200MBq is administered.

**OVERDOSE** Encourage frequent micturition and defecation.

**MARKETING AUTHORISATION HOLDER** GE Healthcare Limited, Nightingales Lane, Pollards Wood, Chalfont St Giles, Buckinghamshire HP8 4SP, UK.

**CLASSIFICATION FOR SUPPLY** Subject to medical prescription (POM).

**MARKETING AUTHORISATION NUMBER** PL00221/0142 (UK).

**UK PRICE** £999.16 (5 vial kit)

**DATE OF REVISION OF TEXT** 05 July 2023

**Adverse events should be reported.**

Reporting forms and information can be found at <https://yellowcard.mhra.gov.uk/>.

Adverse events should also be reported to GE HealthCare at [gpv.drugsafety@ge.com](mailto:gpv.drugsafety@ge.com).