Myoview, tetrofosmin

(Teksten er forkortet i forhold til det af Lægemiddelstyrelsen godkendte produktresumé, dette kan rekvireres vederlagsfrit fra GE Healthcare A/S).
GE Healthcare AS, Oslo, Norge. Dansk repræsentant*: GE Healthcare A/S, Brøndby.*
Indications: This medicinal product is for diagnostic use only. After reconstitution with Sodium Pertechnetate (99mTc) Injection the product is indicated in adults for: *Myocardial Imaging:* Myoview is a myocardial perfusion agent indicated as an adjunct in the diagnosis and localization 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). *Breast Tumour Imaging:* Myoview is indicated as an adjunct to the initial assessments (e.g. palpation, mammography, or alternative imaging modalities and/or cytology) in the characterisation of malignancy of suspected breast lesions where all these other recommended tests were inconclusive.
Contraindications: Hypersensitivity to the active substance or to any of the excipients, Must not be given during pregnancy (see section 4.6 in the Summary of Product Characteristics).
Undesirable effects and risks: *Special warnings and precautions for use*: The possibility of hypersensitivity including anaphylactic / anaphylactoid reactions should always be considered. Advanced life support facilities should be readily available. Careful consideration of the benefit risk ratio in patients suffering from renal impairment and hepatic impairment is required since an increased radiation exposure is possible. Breast lesions less than 1 cm in diameter may not all be detected with scintimammography as the sensitivity of Myoview for the detection of these lesions is 36% (n=5 of 14, 95% CI 13% to 65%) relative to histological diagnosis. A negative examination does not exclude breast cancer especially in such a small lesion. Efficacy in the identification of axillary lesions has not been proven, consequently scintimammography is not indicated for staging breast cancer. In myocardial scintigraphy investigations under stress conditions, the contraindications associated with the induction of stress should be considered. This medical 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.. *Interaction with other medicinal products and other forms of interaction:* No formal studies on the interaction of Myoview with other drugs have been performed. However, no interactions were reported in clinical studies in which Myoview was administered to patients receiving comedication. Drugs which influence myocardial function and/or blood flow, e.g. beta blockers, calcium antagonists or nitrates, can lead to false negative results in diagnosis of coronary artery disease. The results of imaging studies should always, therefore, be considered in the light of current medication. *Pregnancy and lactation: Pregnant women:* Myoview is contraindicated in pregnancy. Radionuclide procedures carried out on pregnant women also involve radiation doses to the foetus. Administration of 250 MBq tetrofosmin (^{99m}Tc) at exercise, followed by 750 MBq at rest results in an absorbed dose to the uterus of 8.1 mGy. A radiation dose above 0.5 mGy (equivalent to the exposure from annual background radiation) would be regarded as a potential risk to the foetus. *Women of childbearing potential:* Before administration of radioactive medicinal products to women of childbearing potential, information should always be sought about pregnancy. Any woman who has missed a period should be assumed to be pregnant until proven otherwise. Where uncertainty exists it is important that radiation exposure should be the minimum consistent with achieving the desired clinical information. Alternative techniques which do not involve ionising radiation should be considered. *Breast feeding: C*onsideration should be given to the possibility of delaying the administration of radionuclide until the mother has ceased breast feeding and to what is the most appropriate choice of radiopharmaceuticals has been made. Tetrofosmin (^{99m}Tc) is present in human milk in small amounts (<1% of maternal dose). If the administration is considered necessary, breastfeeding should be interrupted for 3 to 6 hours and the expressed feeds discarded. *Fertility:* Animal reproductive toxicity studies have not been performed with this product. *Effects on ability to drive and use machines:* No studies on the effects on the ability to drive and use machines have been performed. *Undesirable effects*: Adverse drug reactions following administration of tetrofosmin (^{99m}Tc) are very rare (less than 1 in 10,000). Please refer to Summary of product characteristics for frequency. *Immune*

system disorders: Hypersensitivity reactions including anaphylactoid or anaphylactic reactions and anaphylactic or anaphylactoid shock. *Nervous system disorders:* Headache, dizziness, taste metallic, disturbances of smell. *Eye disorders:* Abnormal vision. *Cardiac disorders:* Tachycardia, chest pain. *Vascular disorders:* Flushing, hypotension. *Respiratory, thoracic and mediastinal disorders:* Dyspnoea, bronchospasm, throat tightness, cough. *Gastrointestinal disorders:* Vomiting, nausea, burning mouth, abdominal pain. *Skin and subcutaneous tissue disorder:* Urticaria, rash, pruritus, erythema, angioedema. *General disorders and administration site condition:* Feeling of warmth, local swelling, face oedema, fever. *Investigations:* White blood cell count increased. Some reactions were delayed by several hours following administration of tetrofosmin (^{99m}Tc). Isolated cases of anaphylactic reaction (less than 1 in 100,000) and severe allergic reaction (single report) have been reported. Since the administered substance quantity is very low, the major risk is caused by the radiation. Exposure to ionising radiation is linked with cancer induction and a potential for developing hereditary defects. As the effective dose is 8.5 mSv when the maximal recommended activity of 1200 MBq is administered these adverse reactions are expected to occur with a low probability.
Overdose: In cases of overdosage of radioactivity frequent micturition and defaecation should be encouraged in order to minimize radiation dosage to the patient.
Dosage: Myoview is not recommended for use in children or adolescents due to lack of data. *Myocardial Imaging:* Patients should be requested to fast overnight or to have only a light breakfast on the morning of the procedure. For diagnosis and localization of myocardial ischaemia (using planar or SPECT techniques) and assessment of left ventricular function using ECG-gated SPECT, the usual procedure involves two intravenous injections of tetrofosmin (^{99m}Tc), one given at peak stress and one given at rest. Detailed description of order of administrations, activity ranges for doses see Summary of Products Characteristics sections 4.2 and 11. As an adjunct in the diagnosis and localization of myocardial infarction, one injection of tetrofosmin (^{99m}Tc) (250-400 MBq) at rest is sufficient. Planar or preferably SPECT imaging should begin no earlier than 15 minutes post-injection. There is no evidence for significant changes in myocardial concentration or redistribution of tetrofosmin (^{99m}Tc), therefore, images may be acquired up to at least four hours post-injection. For planar imaging the standard views (anterior, LAO 40º-45º, LAO 65º-70º and/or left lateral) should be acquired. *Breast Imaging:* For the diagnosis and localization of suspected breast lesions, the recommended procedure involves a single intravenous injection of tetrofosmin (^{99m}Tc) between 500 – 750 MBq. Detailed description of administration, dose, and patient positioning see Summary of Products Characteristics sections 4.2 and 11.
Pharmaceutical form: Kit for radiopharmaceutical preparation.
Pack sizes: 2 x10 ml and 5 x10 ml vials.**Udleveringsgruppe:** B. **Tilskudsstatus:** Ikke tilskudsberettiget.
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