Technetium (99mTc) exametazime is indicated for use with single photon emission tomography (SPECT).

- Brain perfusion SPECT: intravenous use. The radiopharmaceutical should be injected no sooner than 4-6 hours before administration, see section 12.
- Brain perfusion SPECT: 350-500 MBq
- For labelled leukocyte scintigraphy: 200 MBq
- For infectious or inflammatory diseases, the diagnostic target is tissue or structures in which labeled leukocytes are retained.

In infectious or inflammatory diseases, the baseline activity is 51.8 MBq for brain perfusion SPECT, and the minimum activity is 100 MBq.

For labelled leukocyte scintigraphy, the baseline activity is 35 MBq and the minimum activity is 40 MBq.

Because of potential tissue damage extravasal injection of this radioactive product has to be strictly avoided. For multidose use.

- Leukocytes are for intravenous use.

- Sodium 0.52 mg/vial

- Sedimentation agents before they are re-injected into the patient as materials used in cell separation procedures are to be strictly avoided. For multidose use.


classification and code: V09AA01 and V09HA02.

- Infections and inflammatory diseases, the following indications are sufficiently documented:
  - Evaluation of patients with cerebrovascular diseases (specifically acute stroke, chronic ischemia, and transient ischemia)
  - Presurgical localization and normalization of epileptic foci
  - Evaluation of patients with suspected dementia (specifically Alzheimer’s disease and frontotemporal dementia)
  - Evaluation of patients with migraine

- Infections or inflammatory diseases, the diagnostic target is tissue or structures in which labeled leukocytes are retained.

- Lympho-hematic malignancies: patients with lymphoproliferative disorders (with or without implants) and suspected lymphoma or his profession.

- Exercise and sports: in case of physical exertion.

- Sedimentation agents before they are re-injected into the patient as materials used in cell separation procedures are to be strictly avoided. For multidose use.

- Nitrogen

- Other disorder

- No known

- Antiepileptic drugs (e.g., valproic, topiramate)

- Other disorder

- Exposure to ionizing radiation is linked with cancer induction and a potential for development of hereditary cancer.

- As the effective dose is 4.7 mSv when the maximal recommended activity of 500 MBq is administered the radiopharmaceutical may be expected to occur with a low probability.

4.9 Overdose

- In the event of an accident or a radiation overdose with technetium (99mTc) examination, the absorbed dose to the patient should be kept to a minimum by possible increasing the elimination of the radionuclide from the body by frequent micturition and defaecation. It might be helpful to estimate the effective dose radiodestructive treatment.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

- Phagocytosis

- Pharmacokinetics

- Distribution

- Radioactivity

- The injected dose is excised from the kidney and transverse to the liver by the gall bladder.

- Elimination

- No studies on the effects on the ability to drive and use machines have been performed.

- 6.4 Special precautions for use

- Special precautions for storage

- Storage of radiopharmaceuticals should be in accordance with national regulation on radiological material.

- 6.5 Nature and contents of the container

- The product contains 8 ml of Ph.Eur. saline solution (sterile), respectively, for subcutaneous or intravenous injection (500 MBq).

- 6.6 Special precautions for disposal and other handling

- General warnings

- Harsh chemicals, distillation, peroxidation

- Flushing

- Other measures

- 4.1 Therapeutic use

- The radiopharmaceutical does not appear to have any pharmacodynamic activity.

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Radiopharmaceuticals should be received, used and administered only by authorized persons in designated clinical settings. Their receipt, storage, use, transfer and disposal are subject to the regulations and/or appropriate licences of the competent official organization.

The radiopharmaceutical should be provided with an outer package which satisfies both radiation safety and pharmaceutical quality requirements. Appropriate aseptic precautions should be taken.

The irradiating gamma radiation is provided by a 140 keV source with a half-life of 6.02 hours, and is not to be administered directly to the patient without first undergoing the preparation procedure.

For in-vitro separation of leukocytes and subsequent in-vitro labelling with \( {\text{\textsuperscript{99m}}}{\text{\textsuperscript{Tc}}} \) Exametazime injection, Ph. Eur. Adequate shielding is mandatory. Facilities for the radiation processing of medicinal products and irradiation of the operators. Adequate shielding is mandatory.

The data listed below are from ICRP 80:

Fax: +36-23-886-955

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medicinal product and irradiation of the operators. Adequate shielding is mandatory. Facilities for the radiation processing of medicinal products and irradiation of the operators. Adequate shielding is mandatory.

Administration procedures should be carried out in a way to minimise risk of contamination of the patient’s leukocyte count and will vary according to the volume of the initial blood sample.

Efficiency (LE) which is defined as the activity in the cells as a percentage of the sum of the activity in the cells and the activity in the supernatant. Efficiency (LE) is calculated according to the patient's condition. As a guideline it should be: ...

The period of time for erythrocyte sedimentation depends on the patient's condition. As a guideline it should be: ...