Core Safety Profile

CERETEC / STABILISED CERETEC - Technetium (^{99m}Tc) exametazime 500 micrograms

The CSP represents minimum information and should not replace national SPCs.

Contraindications

Hypersensitivity to the active substance or to any of the excipients.

Special warnings and precautions for use.

The possibility of hypersensitivity including serious signs and symptoms of anaphylaxis should always be considered. Advanced life support facilities should be readily available.

Re-injected CERETEC labelled leukocytes only:
When preparing technetium-99m-labelled leukocytes it is essential that cells are washed free of sedimentation agents before they are re-injected into the patient as materials used in cell separation may cause hypersensitivity reactions.

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.

According to the time of conditioning injection for the patient, the content of sodium may in some cases be greater than 1 mmol. This should be taken into account in patients on low sodium diet.

Interaction with other medicinal products and other forms of interaction

No interaction studies have been performed and no drug interactions have been reported to date.

Pregnancy and lactation

Pregnancy:
No data are available on the use of this product in human pregnancy. Animal reproduction studies have not been performed.

When it is necessary to administer 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.

Radionuclide procedures carried out on pregnant women also involve radiation doses to the foetus. Only imperative investigations should be carried out during pregnancy, when the likely benefit exceeds the risk incurred by the mother and the foetus.

Breast-feeding:
Before administering a radioactive medicinal product to a mother who is breast feeding consideration should be given as to whether the investigation could be reasonably delayed until after the mother has ceased breast-

feeding and as to whether the most appropriate choice of radiopharmaceutical has been made, bearing in mind the secretion of activity in breast milk.
If the administration is considered necessary, breast feeding should be interrupted for 12 hours and the expressed feeds discarded.

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

The frequencies of undesirable effects are defined as follows:
Very common (≥1/10), common (≥1/100 to <1/10), uncommon (≥1/1,000 to <1/100), rare (≥1/10,000 to <1/1,000), very rare (<1/10,000) and not known (cannot be estimated from the available data)

Immune system disorders
Not known: Hypersensitivity including rash, erythema, urticaria, angiooedema, pruritus

Re-injected CERETEC labelled leukocytes only:
Not known: Hypersensitivity including rash, erythema, urticaria, angiooedema, pruritus, anaphylactoid reaction or anaphylactoid shock

Nervous system disorders
Not known: Headache, dizziness, paraesthesia

Vascular disorders
Not known: Flushing

Gastrointestinal disorders
Not known: Nausea, vomiting

General disorders and administration site conditions
Not known: Asthenic conditions (e.g., malaise, fatigue)

Exposure to ionising radiation is linked with cancer induction and a potential for development of hereditary defects. As the effective dose is 5.2 mSv when the maximal recommended activity of 555 MBq is administered these adverse events are expected to occur with a low probability.

Overdose

In the event of the administration of a radiation overdose frequent micturition and defecation should be encouraged in order to minimise the absorbed dose to patient.