Eczacıbaşı | monrol

BINDS YOU TO LIFE

Lutetium (^{177}Lu) Chloride

Radiopharmaceutical Precursor, Solution

cGMP CERTIFIED
CURRENT GOOD MANUFACTURING PRACTICE

- Sterile production under GMP conditions
- Sustainable product supply
- Established worldwide distribution network
- Over 20 years of nuclear product manufacturing experience
- Compliant with European Pharmacopoeia
- High product safety with ICP-MS analysis at the end of production
- Accessibility to desired calibration activity at any time

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Manufacturing Date	Every Sunday
Packaging	10 ml Type I, Flat Bottle, Glass Vial
Half-life	6,648 days
Chemical Form	$LuCl_3$ in 0,05 M HCl
Radiochemical Concentration	37 GBq / mL
Radionuclide Purity	≥ 99.9% Lutetium-177 ≤ 0.07% Lutetium-177m ≤ 0.01% Other Impurities
Chemical Purity	Cu ≤ 1.0 µg/GBq Fe ≤ 0.5 µg/GBq Pb ≤ 0.5 µg/GBq Zn ≤ 1.0 µg/GBq
Shelf life	8 days after production

ECZACIBAŞI-MONROL NUCLEAR PRODUCTS CO.

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About ECZACIBAŞI-MONROL

Eczacıbaşı-Monrol Nuclear Products leads the development of Turkey's nuclear medicine market through the production of high-quality radiopharmaceuticals for diagnosis and treatment. Eczacıbaşı-Monrol Nuclear Products also carries out its expertise all around the world with logistic infrastructure.

Eczacıbaşı-Monrol's main objective is to improve quality of life for people significantly with innovative approach for the diagnosis and treatment of serious diseases.

cGMP CERTIFIED | TÜV | TÜV | TÜV | kiwa certified OHSAS 18001 | PIC/S

Revision date: 00 / 2019

1 mL of LUTETIUM CHLORIDE contains 37 GBq Lutetium (^{177}Lu) Chloride in the calibration hour of 37 GBq/mL radiopharmaceutical precursor solution. Each vial contains solution whose volume varies between 0,1 mL – 5 mL equivalent to an activity in the range of 3,7 GBq – 185 GBq in each calibration hour. **Excipients:** Hydrochloric acid solution **Indication:** This medical product is used only for radiolabelling carrier molecules specially developed for radiolabelling with this radionuclide. **Posology:** The quantity of LUTETIUM CHLORIDE required for radiolabelling and the quantity of the product to be radiolabelled with Lutetium (^{177}Lu) are determined depending on the product to be radiolabelled and its intended use. **Primary adverse effects:** Exposure to ionizing radiation must be justifiable for each patient on the basis of probable clinic benefit.Blood and lymph system diseases: Very common: Anaemia, thrombocytopenia, leucopenia and lymphopenia. Endocrine diseases: Frequency is unknown: Carcinoid crisis. Gastrointestinal diseases: Very common: Nausea and vomiting, Benign and malignant neoplasms: Common: Refractory cytopenia accompanying multi-indexed dysplasia (myelodysplastic syndrome). Uncommon: Acute myeloid leukaemia. Skin and subcutaneous tissue diseases: Very common: Alopecia and short term desert mouth were reported. **Interactions:** No study has been carried out for interaction of LUTETIUM CHLORIDE with other medical products. Please refer to the summary of product characteristics/package insert of the labelled product for more detailed information about interactions related to the use of medical products labelled with LUTETIUM CHLORIDE. **Incompatibilities:** All glass materials, injector needles etc. which will be used for the preparation of the radiolabelled product must be thoroughly cleaned in order to guarantee that they are free from trace metal impurities. **Contraindications:** Hypersensitivity to the active ingredient or any listed excipients. Please refer to the summary of product characteristics/package insert of the medical product to be labelled to obtain information about the contraindications of the medical product radiolabelled with LUTETIUM CHLORIDE in the pregnancy period or in case of suspicion of pregnancy or if the probability of pregnancy has not been eliminated. **WARNINGS:** RADIOPHARMACEUTICALS MUST ONLY BE APPLIED BY NUCLEAR MEDICINE SPECIALISTS IN NUCLEAR MEDICINE CENTRES. Radioactive medical products must be prepared so that they will satisfy both requirements of radiation safety and pharmaceutical quality. Proper aseptic measures must be taken. Paediatric population: The medical products labelled with LUTETIUM CHLORIDE must be used for children and adolescents below the age of 18. Myelodysplastic syndrome and acute myeloid leukaemia: Myelodysplastic syndrome (MDS) and acute myeloid leukaemia (AML) incidents were reported following the treatment with Lutetium (^{177}Lu) peptide receptor radionuclide for neuroendocrine tumours. Myelosupression: During the radiogland treatment with LUTETIUM CHLORIDE, anaemia, thrombocytopenia, leukopenia, lymphopenia and less commonly neutropenia may take place. Renal irradiation: Renal function must be regularly evaluated and renal protection must be considered both at the beginning and during the treatment in compliance with the clinical guideline. Hepatoxicity: Hepatoxicity incidents were reported patients with liver metastasis who were treated with ^{177}Lu peptide receptor radionuclide treatment for neuroendocrine tumours in post-marketing experiences and literature. The liver function must be regularly monitored during the treatment. The dose may be required to be reduced for any patients whose livers are affected thereby. Extravasation: In case of extravasation, infusion of the medical product must immediately be stopped and the nuclear medicine specialist must be informed without delay. Lactation period: If the administration is deemed necessary, lactation must be suspended and breast milk must be disposed by way of milking. **Effects on driving and machine operation:** The information on its effect on driving and machine operation following treatment with the medical product labelled with LUTETIUM CHLORIDE is provided in the summary of product characteristics/package insert of the product to be labelled. **Shelf life:** 8 days starting from the date of production. **Special warnings for storage:** Keep the product in its lead shield below 25ºC. It must be kept in its original package as required for protection against radiation. Radiopharmaceuticals must be stored in compliance with the national legislation concerning radioactive substances.