LutaPol

Lutetium ($^{177}$Lu) chloride radiopharmaceutical precursor, solution

Marketing authorisation holder
Narodowe Centrum Badań Jądrowych
ul. Andrzeja Soltana 7
05-400 Otwock
Tel. (+48) 22 718 07 00
Fax (+48) 22 718 03 50

Marketing authorisation number 22081
issued by President of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products

Classification for supply:
Medicinal product subject to medicinal prescription
Pharmaceutical form
Radiopharmaceutical precursor, solution.
Clear, colourless solution.

Qualitative and quantitative composition
Each vial contains 0,925-37 GBq Lutetium (\(^{177}\text{Lu}\)) on the reference date and time (corresponding to 1,86 – 74 micrograms of lutetium as lutetium chloride in the volume from 0,010 ml to 2 ml in hydrochloric acid solution).
Lutetium (\(^{177}\text{Lu}\)) decays to stable Hafnium (\(^{177}\text{Hf}\)). It decays by emission of \(\beta\)-particles with maximum energy 498 keV (average 149,2 keV) and emission of gamma radiation with prominent energies 208 keV (10,4%) and 113 keV (6,2%). Lutetium (\(^{177}\text{Lu}\)) has a half-life of 6,65 days.
Lutetium (\(^{177}\text{Lu}\)) is produced in nuclear reactor by neutron irradiation of Lutetium enriched in isotope (\(^{178}\text{Lu}\)). Such obtained Lutetium (\(^{177}\text{Lu}\)) contains stable Lutetium (\(^{177}\text{Lu}\)) as carrier. The specific activity of Lutetium (\(^{177}\text{Lu}\)) in pharmaceutical product LutaPol is higher than 500 GBq/mg of Lutetium.

Therapeutic indications
To be used only for the radiolabelling of medicinal products, which have been specifically developed and authorised for radiolabelling with this radionuclide.
Radiopharmaceutical precursor - Not intended for direct use in patients.

Posology and method of administration
Posology
The quantity of LutaPol required for radiolabelling and the quantity of Lutetium (\(^{177}\text{Lu}\))-labelled medicinal product that is subsequently administered will depend on the medicinal product radiolabelled and its intended use. Refer to the Summary of Product Characteristics/package leaflet of the particular medicinal product to be radiolabelled.
Method of administration
LutaPol is intended for in vitro labelling of medicinal products which are subsequently administered by the approved route.

Contraindications
Do not administer LutaPol directly to the patient.
LutaPol is contraindicated in the following cases:
- Hypersensitivity to Lutetium (\(^{177}\text{Lu}\)) chloride or to any of the excipients
- Established or suspected pregnancy, breast-feeding, planning pregnancy
- When pregnancy has not been excluded
For information on contraindications to particular Lutetium (\(^{177}\text{Lu}\))-labelled medicinal products prepared by radiolabelling with LutaPol refer the Summary of Product Characteristics/package leaflet of the particular medicinal product to be radiolabelled.

Undesirable effects
Possible adverse reactions following the intravenous administration Lutetium (\(^{177}\text{Lu}\))-labelled medicinal product prepared by radiolabelling with LutaPol, will be dependent on the specific medicinal product being used. Such information will be supplied in the Summary of Product Characteristics/package leaflet of the medicinal product to be radiolabelled. For each patient, exposure to ionising radiation must be justifiable on the basis of likely clinical 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 therapeutic result.
Exposure to ionising radiation is linked with cancer induction and a potential for development of hereditary defects. The radiation dose resulting from therapeutic exposure may result in higher incidence of cancer and mutations. In all cases, it is necessary to ensure that the risks of the radiation are less than from the disease itself.

Special warnings and precautions for use
The contents of the vial of LutaPol is not to be administered directly to the patient but must be used for the radiolabelling of carrier molecules, such as monoclonal antibodies, peptides or other substrates.
For each patient, the radiation exposure must be justifiable by the likely benefit from the pharmaceutical procedure with use of this pharmaceutical. The quantity of LutaPol required for radiolabelling and the quantity of Lutetium (\(^{177}\text{Lu}\))-labelled medicinal product that is administered to patient, should be as low as reasonably achievable to obtain the required therapeutic effect.
For information concerning special warnings and special precautions for use of Lutetium (\(^{177}\text{Lu}\))-labelled medicinal products refer to the Summary of Product Characteristics/package leaflet of the medicinal product to be radiolabelled.

Paediatric population
Particular care should be taken when administering radioactive medicinal products to children and adolescents (from 2 to 16 years old).

List of excipients
Hydrochloric acid concentrated
Water for injection

Shelf life
7 days from the date of manufacture.

Special precautions for storage
Store below 25°C.
Store in the original package.
Storage should be in accordance with national regulation on radioactive material.

Nature and contents of container
Colourless type I glass vial of 2 ml sealed with rubber stopper and an aluminium crimp cap, placed in lead shielding container.
Pack size: 1 vial
During storage, due to ionizing radiation, the vial may change colour into yellow-brown. This discoloration has no influence into the product quality.