ItraPol

Yttrium (90Y) chloride radiopharmaceutical precursor solution

Marketing authorisation holder
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Marketing authorisation number 22069
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 Yttrium ($^{90}$Y) on the reference date and time (corresponding to 46 - 1840 nanograms of Yttrium ($^{90}$Y)) in a volume 0.010 - 2 ml as Yttrium ($^{90}$Y) chloride in a diluted hydrochloric acid. Yttrium ($^{90}$Y) chloride is produced by decay of its radioactive precursor Strontium ($^{90}$Sr). It decays by emission of beta radiation with maximum energy 2.281 MeV (99.98 %), to stable Zirconium ($^{90}$Zr). Yttrium ($^{90}$Y) has a half-life of 2.67 days (64.1 hours).

**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 ItraPol required for radiolabelling and the quantity of Yttrium ($^{90}$Y)-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**
ItraPol is intended for *in vitro* labelling of medicinal products which are subsequently administered by the approved route.

**Contraindications**
Do not administer ItraPol directly to the patient. ItraPol is contraindicated in the following cases:
- Hypersensitivity to Yttrium ($^{90}$Y) chloride or to any of the excipients
- Yttrium ($^{90}$Y)-labelled medicinal products are contraindicated in the following cases:
  - Established or suspected pregnancy or when pregnancy has not been excluded
  - Breast-feeding
For information on contraindications to particular Yttrium ($^{90}$Y)-labelled medicinal products prepared by radiolabelling with ItraPol 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 of a Yttrium ($^{90}$Y)-labelled medicinal product prepared by radiolabelling with ItraPol, will be dependent on the specific medicinal product being used. Such information will be specified 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, should in every case be as low as reasonably achievable to obtain the required therapeutic effect. 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 ItraPol 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 therapeutic procedure with use of this radiopharmaceutical. The quantity of ItraPol required for radiolabelling and the quantity of Yttrium ($^{90}$Y)-labelled medicinal product that is subsequently administered, should in every case be as low as reasonably achievable to obtain the required therapeutic effect. For information concerning special warnings and special precautions for use of Yttrium ($^{90}$Y)-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 injections

**Shelf life**
7 days from the date of manufacture.

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

**Nature and contents of container**
Colourless type I glass vial of 2 ml volume closed with a rubber stopper and aluminium seal, placed in a shielding lead container.

**Pack size:** 1 vial
During storage, due to ionizing radiation, the vial may change color into yellow-brown. This discoloration has no influence into the product quality.