**PACKAGE LEAFLET: INFORMATION FOR THE PATIENT**

**ItraPol radiopharmaceutical precursor, solution**

Yttrium ($^{90}$Y) chloride

**Read all of this leaflet carefully before you are given this medicine because it contains important information for you.**
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your nuclear medicine doctor who will supervise the procedure.
- If you get any side effects, talk to your nuclear medicine doctor. This includes any possible side effects not listed in this leaflet. See section 4.

**What is in this leaflet:**



## 1. What ItraPol is and what it is used for

ItraPol is a radiopharmaceutical product for therapy and is only used in combination with another medicine which targets specific body cells. When the target is reached, ItraPol gives tiny radiation doses to these specific sites.

For further information regarding the treatment and possible effects caused by the $^{90}$Y radiolabelled medicinal product, please refer to the package leaflet of the medicinal product to be radiolabelled.

## 2. What you need to know before ItraPol is used

**ItraPol must not be used**
- if you are allergic to Yttrium ($^{90}$Y) chloride or any of the other ingredients of this medicine (listed in section 6).
- if you are pregnant or believe you may be pregnant (see below).
- If you are breast-feeding

**Warnings and precautions**

ItraPol is a radiopharmaceutical product used only in combination with another medicinal product. It is not intended for direct use in patients.

**Children and adolescents**

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

**Other medicines and ItraPol**

Tell your nuclear medicine doctor if you are taking, have recently taken or might take any other medicines.

No interactions of Yttrium ($^{90}$Y) chloride with other medicines are known as no clinical studies are available.

**Pregnancy and breast-feeding**

ItraPol is contraindicated in pregnancy.

You must inform the nuclear medicine doctor before the administration of ItraPol if there is a possibility you might be pregnant, if you have missed your period or if you are breast-feeding. When in doubt, it is important to consult your nuclear medicine doctor who will supervise the procedure.

Your doctor will consider alternative techniques which do not involve ionising radiation.

Women of childbearing potential have to use effective contraception during and in a short period after treatment.

If you are breast-feeding, and if the administration of radiopharmaceutical is considered necessary, your doctor will ask you to stop breast-feeding. Ask your nuclear medicine doctor for advice before taking any medicine.

**Driving and using machines**

No data.

## 3. How ItraPol is used

Radiopharmaceuticals may be administered only by authorized health-care personnel.

There are strict laws on the use, handling and disposal of radiopharmaceutical products. ItraPol will only be used in special controlled areas. This product will only be handled and given to you by people who are trained and qualified to use it safely. These persons will take special care for the safe use of this product and will keep you informed of their actions.

Your doctor will not administer ItraPol directly.

**Dose**
The nuclear medicine doctor supervising the procedure will decide on the quantity of ItraPol, to be used in your case. It will be the smallest quantity necessary to get the desired effect.

**Administration of ItraPol and conduct of the procedure**
ItraPol is a radiopharmaceutical product used only in combination with another medicine which targets specific body cells. It is administered only by authorized health-care personnel. ItraPol is intended for radiolabelling of medicinal products to treat specific diseases, which are subsequently administered by approved route.

**If you have been given more ItraPol than you should**
An overdose is unlikely, because you will only receive a dose of product precisely controlled by the nuclear medicine doctor supervising the procedure. However in the case of an overdose, you will receive appropriate treatment.
Should you have any further questions on the use of ItraPol, please ask the nuclear medicine doctor who supervises the procedure.

**4. Possible side effects**
Like all medicines, this medicine can cause side effects, although not everybody gets them.
The exposure to ionising radiation is associated with the risk of cancer (in the case of high radioactivity used) and hereditary defects.
For further information regarding the possible side effects caused by the $^{90}$Y radiolabelled medicinal product, please refer to the package leaflet of the medicinal product to be radiolabelled.

Reporting of side effects
If you get any side effects, talk to your nuclear medicine doctor. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system.
Adverse reactions may be reported to Marketing Authorization Holder.
By reporting side effects you can help provide more information on the safety of this medicine.

**5. How ItraPol is stored**
You will not have to store this medicine. This medicine is stored under the responsibility of the specialist in appropriate premises. Storage of radiopharmaceuticals will be in accordance with national regulation on radioactive materials.

The following information is intended for the specialist only.
Keep this medicine out of the sight and reach of children.
ItraPol must not be used after the expiry date which is stated on the label.

**6. Contents of the pack and other information**
**What ItraPol contains**
- The active substance is Yttrium ($^{90}$Y) chloride.
- 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] as Yttrium [$^{90}$Y] chloride).
- The other ingredients are hydrochloric acid (concentrated) and water for injections.

**What ItraPol looks like and contents of the pack**
Colourless type I glass vial of 2 ml volume closed with a rubber stopper and aluminium seal, placed in a lead shielding container.
Radiopharmaceutical precursor, solution.
Colourless, clear solution.

**Marketing Authorisation Holder and Manufacturer**
Narodowe Centrum Badań Jądrowych
ul. Andrzeja Sołtana 7
05-400 Otwock,
Poland
Tel. (22) 718 07 00
Fax (22) 718 03 50
e-mail: polatom@polatom.pl

**This leaflet was last revised in:** 05.06.2019

The complete Summary of Product Characteristics (SmPC) of ItraPol is provided as a separate document in the product package, with the objective to provide healthcare professionals with other additional scientific and practical information about the administration and use of this radiopharmaceutical.