

B. PACKAGE LEAFLET

PACKAGE LEAFLET: INFORMATION FOR THE USER

Yttriga radiopharmaceutical precursor, solution.

Yttrium (^{90}Y) chloride

Read all of this leaflet carefully before you start using this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Yttriga is and what it is used for
2. Before you use Yttriga
3. How to use Yttriga.
4. Possible side effects
5. How to store Yttriga
6. Further information

1. WHAT YTTRIGA IS AND WHAT IT IS USED FOR

Yttriga is a radioactive medicine used in combination with another medicine which targets specific body cells.

When the target is reached, Yttriga gives tiny radiation doses to these specific sites.

For further information regarding the treatment and possible effects caused by the radiolabelled medicinal product, please refer to the package leaflet of the medicinal product used as combination partner.

2. BEFORE YOU USE YTTRIGA

Do not use Yttriga:

- if you are allergic (hypersensitive) to Yttrium (^{90}Y) chloride or any of the other ingredients of Yttriga.
- if you are pregnant or if there is a possibility that you may be pregnant (see below).

Take special care with Yttriga

- Yttriga is a radioactive medicine and is only used in combination with another medicinal product. It is not intended for direct use in patients.
- Because there are strict laws covering the use, handling and disposal of radiopharmaceuticals, Yttriga will always be used in a hospital or a similar setting. It will only be handled and administered by people who are trained and qualified in the safe handling of radioactive material.

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

Taking other medicines

Please tell your doctor or pharmacist, if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

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

Pregnancy

Yttriga is contraindicated in Pregnancy.

Please tell your doctor if there is any possibility that you are pregnant. If you have missed a period, you should assume to be pregnant until a pregnancy test conducted is negative.

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

Women of childbearing potential should use effective contraception during and after treatment.

Breast-feeding

Your doctor will ask you to stop breast-feeding.

Ask your doctor or pharmacist for advice before taking any medicine.

3. HOW TO USE YTTRIGA

Your doctor will not administer Yttriga directly.

Dose

Your physician will decide on the amount of Yttriga, which you will receive for the treatment.

Method of administration

Yttriga is intended for radiolabelling of medicinal products to treat specific diseases, which are subsequently administered by approved route.

If Yttriga is administered inadvertently

Yttriga is administered after being combined with another medicine by your doctor under strictly controlled conditions. The risk to receive a possible overdose is small. However, should this occur, you will receive appropriate treatment from your doctor.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Yttriga can cause side effects, although not everybody gets them.

For more information, refer to the package leaflet of the particular medicinal product to be radiolabelled.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Reporting of side effects

If you get any side effects, talk to your <doctor> <or> <,> <pharmacist> <or nurse>. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via **the national reporting system** listed in [Appendix V](#). By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE YTTRIGA

Keep out of the reach and sight of children.

Do not use Yttriga after the expiry date and time which is stated on the label after EXP.

Store in accordance with local regulations for radioactive substances.

Any unused product or waste material should be disposed of in accordance with local requirements.

6. FURTHER INFORMATION

What Yttriga contains

- The active substance is Yttrium (^{90}Y) chloride.
- 1 ml sterile solution contains 0.1-300 GBq Yttrium (^{90}Y) on the reference date and time (corresponding to 0.005-15 micrograms of Yttrium [^{90}Y]) (as Yttrium [^{90}Y] chloride).
- The other ingredient is hydrochloric acid (0.04 M).

What Yttriga looks like and contents of the pack

Colourless type I glass vial of 3 ml with a V-shaped bottom or a colourless type I glass vial of 10 ml with a flat bottom with a silicon stopper, closed with an aluminium seal.

Radiopharmaceutical precursor, solution.
Colourless clear sterile solution.

Marketing Authorisation Holder

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This leaflet was last revised in {MM/YYYY}.

Other sources of information

Detailed information on this medicine is available on the European Medicines Agency web site:
<http://www.ema.europa.eu>.

This leaflet is available in all EU/EEA languages on the European Medicines Agency website.