ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Yttriga radiopharmaceutical precursor, solution.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

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).

Each 3ml vial contains 0.1-300 GBq, corresponding to 0.005-15 micrograms of Yttrium (^{90}Y), at reference date and time. The volume is 0.02-3 ml.
Each 10ml vial contains 0.1-300 GBq, corresponding to 0.005-15 micrograms of Yttrium (^{90}Y), at reference date and time. The volume is 0.02-5 ml.
The theoretical specific activity is 20 GBq/microgram of Yttrium (^{90}Y) (see section 6.5).

Yttrium (^{90}Y) chloride is produced by decay of its radioactive precursor Strontium (^{90}Sr). It decays by emission of beta radiation of 2.281 MeV (99.98 %) of maximal energy to stable Zirconium (^{90}Zr). Yttrium (^{90}Y) has a half-life of 2.67 days (64.1 hours).

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Radiopharmaceutical precursor, solution.

Clear colourless solution, free of particulate matter.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

To be used only for the radiolabelling of carrier molecules, which have been specifically developed and authorised for radiolabelling with this radionuclide.

Radiopharmaceutical precursor - Not intended for direct use in patients.

4.2 Posology and method of administration

Yttriga is only to be used by specialists experienced with *in vitro* radiolabelling.

Posology

The quantity of Yttriga 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

Yttriga is intended for *in vitro* labelling of medicinal products which are subsequently administered by the approved route.
Further information on the preparation of the product is given in section 12.

4.3 Contraindications

Do not administer Yttriga directly to the patient.
Yttriga 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 case:
- Established or suspected pregnancy or when pregnancy has not been excluded (see section 4.6)

For information on contraindications to particular Yttrium (^{90}Y)-labelled medicinal products prepared by radiolabelling with Yttriga refer the Summary of Product Characteristics/package leaflet of the particular medicinal product to be radiolabelled**.**

4.4 Special warnings and precautions for use

The contents of the vial of Yttriga 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.

Radiopharmaceuticals should be received, used and administered only by authorised persons in designated clinical settings and receipt, storage, use, transfer and disposal are subject to the regulations and appropriate licences of the competent authorities.

Radiopharmaceuticals should be prepared by the user in a manner which satisfies both radiation safety and pharmaceutical quality requirements.

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.

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

4.5 Interaction with other medicinal products and other forms of interaction

No interaction studies of Yttrium (^{90}Y) chloride with other medicinal products have been performed, because Yttriga is a precursor solution for radiolabelling medicinal products.

For information concerning interactions associated with the use of Yttrium (^{90}Y)-labelled medicinal products refer to the Summary of Product Characteristics/package leaflet of the medicinal product to be radiolabelled.

4.6 Fertility, pregnancy and lactation

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

Pregnancy
Yttrium (^{90}Y)-labelled medicinal products are contraindicated in established or suspected pregnancy or when pregnancy has not been excluded (see section 4.3).

Breast-feeding
Before administering a radioactive medicinal product to a mother who is breast-feeding, consideration should be given to whether the investigation could be reasonably delayed until the mother has ceased breast-feeding. If the administration cannot be delayed, a lactating mother should be advised to stop breast-feeding.

Further information concerning the use of a Yttrium (^{90}Y)-labelled medicinal products in pregnancy and breast-feeding is specified in the Summary of Product Characteristics of the medicinal product to be radiolabelled.

Fertility
Further information concerning the use of a Yttrium (^{90}Y)-labelled medicinal concerning fertility is specified in the Summary of Product Characteristics of the medicinal product to be radiolabelled.

4.7 Effects on ability to drive and use machines

Effects on ability to drive and to use machines following treatment by Yttrium (^{90}Y)-labelled medicinal products will be specified in the Summary of Product Characteristics/package leaflet of the medicinal product to be radiolabelled.

4.8 Undesirable effects

Possible adverse reactions following the intravenous administration of a Yttrium (^{90}Y)-labelled medicinal product prepared by radiolabelling with Yttriga, 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.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the national reporting system listed in Appendix V.

4.9 Overdose

The presence of free Yttrium (^{90}Y) chloride in the body after an inadvertent administration of Yttriga will lead to increased bone marrow toxicity and haematopoietic stern cell damage.
Therefore, in case of an inadvertent administration of Yttriga, the radiotoxicity for the patient must be reduced by immediate (i. e. within 1 hour) administration of preparations containing chelators like Ca-DTPA or Ca-EDTA in order to increase the elimination of the radionuclide from the body.

The following preparations must be available in medical institutions, which use Yttriga for labelling of carrier molecules for therapeutic purposes:
- Ca-DTPA (Trisodium calcium diethylenetriaminepentaacetate) or
- Ca-EDTA (Calcium disodium ethylenediaminetetraacetate)

These chelating agents suppress yttrium radiotoxicity by an exchange between the calcium ion and the yttrium due to their capacity of forming water soluble complexes with the chelating ligands (DTPA, EDTA). These complexes are rapidly eliminated by the kidneys.

1 g of the chelating agents should be administered by slow intravenous injection over 3 – 4 minutes or by infusion (1 g in 100 – 250 ml of dextrose, or normal saline).

The chelating efficacy is greatest immediately or within one hour of exposure when the radionuclide is circulating in or available to tissue fluids and plasma. However, a post-exposure interval > 1 hour does not preclude the administration and effective action of chelator with reduced efficiency. Intravenous administration should not be protracted over more than 2 hours.

In any case the blood parameters of the patient have to be monitored and the appropriate actions immediately taken if there is evidence of damage to the blood marrow.

The toxicity of the free Yttrium (^{90}Y) due to in-vivo release from the labelled biomolecule in the body during therapy could be reduced by post-administration of chelating agents.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Other therapeutic radiopharmaceuticals, ATC code: V10X.
The pharmacodynamic properties of Yttrium (^{90}Y)-labelled medicinal products prepared by radiolabelling with Yttriga, prior to administration, will be dependent on the nature of the medicinal product to be radiolabelled. Refer to the Summary of Product Characteristics/package leaflet of the particular medicinal product to be radiolabelled.

5.2 Pharmacokinetic properties

The pharmacokinetic properties of Yttrium (^{90}Y)-labelled medicinal products prepared by radiolabelling with Yttriga, prior to administration, will be dependent on the nature of the medicinal product to be radiolabelled.

In the rat, following intravenous administration, Yttrium (^{90}Y) chloride is rapidly cleared from the blood. At 1 and 24 hours, blood radioactivity decreases from 11.0 % to 0.14 % of the administered activity. The two main organs where Yttrium (^{90}Y) chloride distributes are the liver and bones. In the liver, 18 % of the injected activity is taken up 5 min after injection. Liver uptake decreases then to 8.4 % 24 hours after injection. In bone, percentage of injected activity increases from 3.1 % at 5 min to 18 % at 6 hours and then decreases with time. Faecal and urinary elimination is slow: about 31 % of the administered activity is eliminated in 15 days.

5.3 Preclinical safety data

The toxicological properties of Yttrium (^{90}Y)-labelled medicinal products prepared by radiolabelling with Yttriga prior to administration, will be dependent on the nature of the medicinal product to be radiolabelled.

There are no data available on the toxicity of Yttrium (^{90}Y) chloride nor on its effects on reproduction in animals or its mutagenic or carcinogenic potential.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Hydrochloric acid (0.04 M)

6.2 Incompatibilities

Radiolabelling of medicinal products, such as monoclonal antibodies, peptides or other substrates, with Yttrium (^{90}Y) chloride is very sensitive to the presence of trace metal impurities.
It is important that all glassware, syringe needles etc, used for the preparation of the radiolabelled medicinal product are thoroughly cleaned to ensure freedom from such trace metal impurities. Only syringe needles (for example, non-metallic) with proven resistance to dilute acid should be used to minimise trace metal impurity levels.

6.3 Shelf life

Up to 12 days from the date of manufacture.

6.4 Special precautions for storage

Storage should be in accordance with national regulation on radioactive material.

6.5 Nature and contents of container

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

Pack size: 1 vial
Not all presentations may be marketed.

6.6 Special precautions for disposal

The vial may contain high pressure due to radiolysis (see section 12).

7. MARKETING AUTHORISATION HOLDER

Eckert & Ziegler Radiopharma GmbH
Robert-Rössle-Str. 10
D-13125 Berlin
Germany

8. MARKETING AUTHORISATION NUMBER(S)

EU/1/05/322/001 (3 ml V-shaped vial)
EU/1/05/322/002 (10 ml flat bottom vial)

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 19/01/2006
Date of renewal: 06/01/2011

10. DATE OF REVISION OF THE TEXT

11. DOSIMETRY

The radiation dose received by the various organs following intravenous administration of an Yttrium (^{90}Y)-labelled medicinal product is dependent on the specific medicinal product being

radiolabelled. Information on radiation dosimetry of each different medicinal product following administration of the radiolabelled preparation will be available in the Summary of Product Characteristics/package leaflet of the particular medicinal product to be radiolabelled.

The dosimetry table below is presented in order to evaluate the contribution of non-conjugated Yttrium (^{90}Y) to the radiation dose following the administration of Yttrium (^{90}Y)-labelled medicinal product or resulting from an accidental intravenous injection of Yttriga.

The dosimetry estimates were based on a rat distribution study and the calculations were effected in accordance with MIRD/ICRP 60 recommendations. Time-points for measurements were 5 min, 1, 6, 24, 96 and 360 hours.

Absorbed dose per unit activity administered (mGy/MBq)						
Organ	**Adult (70 kg)**	**15 years (50 kg)**	**10 years (30 kg)**	**5 years (17 kg)**	**1 year (10 kg)**	**Newborn (5 kg)**
Adrenals	7.23 E-01	1.09 E+00	2.53 E+00	3.62 E+00	7.23 E+00	2.17 E+01
Blood	4.20 E-02	6.29 E-02	1.47 E-01	2.10 E-01	4.19 E-01	1.26 E+00
Bone marrow	2.58 E+00	3.88 E+00	9.05 E+00	1.29 E+01	2.58 E+01	7.75 E+01
Brain	8.60 E-03	1.29 E-02	3.01 E-02	4.30 E-02	8.60 E-02	2.58 E-01
Carcass	5.82 E-01	8.72 E-01	2.04 E+00	2.91 E+00	5.82 E+00	1.75 E+01
Colon	2.30 E-02	3.46 E-02	8.06 E-02	1.15 E-01	2.30 E-01	6.91 E-01
Femur	7.76 E+00	1.16 E+01	2.72 E+01	3.88 E+01	7.76 E+01	2.33 E+02
Gastro-intestinal content	1.22 E-01	1.83 E-01	4.26 E-01	6.09 E-01	1.22 E+00	3.66 E+00
Heart	2.53 E-01	3.79 E-01	8.85 E-01	1.26 E+00	2.53 E+00	7.59 E+00
Ileum	1.16 E-02	1.74 E-02	4.06 E-02	5.81 E-02	1.16 E-01	3.48 E-01
Kidneys	2.35 E+00	3.53 E+00	8.24 E+00	1.18 E+01	2.35 E+01	7.06 E+01
Liver	1.27 E+00	1.91 E+00	4.46 E+00	6.37 E+00	1.27 E+01	3.82 E+01
Lungs	4.23 E-01	6.34 E-01	1.48 E+00	2.11 E+00	4.23 E+00	1.27 E+01
Ovaries	3.33 E-01	4.99 E-01	1.17 E+00	1.66 E+00	3.33 E+00	9.99 E+00
Pancreas	7.90 E-02	1.18 E-01	2.76 E-01	3.95 E-01	7.90 E-01	2.37 E+00
Skeletal muscle	6.12 E-04	9.17 E-04	2.14 E-03	3.06 E-03	6.12 E-03	1.83 E-02
Skin	1.02 E-01	1.53 E-01	3.58 E-01	5.11 E-01	1.02 E+00	3.06 E+00
Spleen	4.90 E-01	7.36 E-01	1.72 E+00	2.45 E+00	4.90 E+00	1.47 E+01
Stomach	6.47 E-02	9.70 E-02	2.26 E-01	3.23 E-01	6.47 E-01	1.94 E+00
Thymus	7.34 E-02	1.10 E-01	2.57 E-01	3.67 E-01	7.34 E-01	2.20 E+00
Thyroids	9.99 E-01	1.50 E+00	3.50 E+00	5.00 E+00	9.99 E+00	3.00 E+01
Urinary bladder	3.62 E-01	5.44 E-01	1.27 E+00	1.81 E+00	3.62 E+00	1.09 E+01
Uterus	1.51 E-02	2.26 E-02	5.28 E-02	7.55 E-02	1.51 E-01	4.53 E-01
Effective Dose (mSv/MBq)	**6.65 E-01**	**9.98 E-01**	**2.33 E+00**	**3.33 E+00**	**6.65 E+00**	**1.99 E+1**

For this product the effective dose to a 70 kg adult resulting from an intravenously injected activity of 1 GBq is 665 mSv.

12. INSTRUCTIONS FOR PREPARATION OF RADIOPHARMACEUTICALS

Before use, packaging and radioactivity should be checked. Activity may be measured using an ionisation chamber. Yttrium (^{90}Y) is a beta pure emitter. Activity measurements using an ionisation chamber are very sensitive to geometric factors and, therefore, should be performed only under geometric conditions which have been appropriately validated.

Usual precautions regarding sterility and radioactivity should be respected.

The vial should never be opened and must be kept inside its lead shielding. The product should be aseptically withdrawn through the stopper using sterilised single use needle and syringe after disinfecting the stopper.
Appropriate aseptic precautions should be taken, complying with the requirements of Good Pharmaceutical Manufacturing Practice, in order to maintain the sterility of Yttriga and to maintain sterility throughout the labelling procedures.
The administration of radioactive medicinal products creates risks for other persons from external radiation or contamination from spills of urine, vomiting, etc. Radiation protection precautions in accordance with national regulations must therefore be taken.

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

Detailed information on this product is available on the website of the European Medicines Agency http://www.ema.europa.eu

ANNEX II

A. MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE

B. CONDITIONS OF THE MARKETING AUTHORISATION

A MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE

Name and address of the manufacturer responsible for batch release

Eckert & Ziegler Radiopharma GmbH
Branch Braunschweig
Gieselweg 1
D-38110 Braunschweig
Germany

B CONDITIONS OF THE MARKETING AUTHORISATION

- **CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IMPOSED ON THE MARKETING AUTHORISATION HOLDER**

Medicinal product subject to restricted medical prescription (See Annex I: Summary of Product Characteristics, section 4.2)

- **CONDITIONS OR RESTRICTIONS WITH REGARD TO THE SAFE AND EFFECTIVE USE OF THE MEDICINAL PRODUCT**

Not applicable.

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING AND THE IMMEDIATE PACKAGING

TIN CAN AND LEAD POT

1. NAME OF THE MEDICINAL PRODUCT

Yttriga radiopharmaceutical precursor, solution.
Yttrium (^{90}Y) chloride

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Yttrium (^{90}Y) chloride

Act.: (Y) GBq/vial

Cal.: {DD/MM/YYYY} (12h CET)

Specific activity at calibration: (Y) GBq/vial

3. LIST OF EXCIPIENTS

Hydrochloric acid (0.04 M)

4. PHARMACEUTICAL FORM AND CONTENTS

Radiopharmaceutical precursor, solution.

1 vial
Vol.: {Z} ml

5. METHOD AND ROUTE(S) OF ADMINISTRATION

For *in vitro* radiolabelling. Read the package leaflet before use.
NOT INTENDED FOR DIRECT ADMINISTRATION TO PATIENTS

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE REACH AND SIGHT OF CHILDREN

Keep out of the reach and sight of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

The vial may contain high pressure due to radiolysis.

8. EXPIRY DATE

EXP {MM/YYYY} (12h CET)

9. SPECIAL STORAGE CONDITIONS

Store in the original package.

Storage should be in accordance with local regulations for radioactive substances.

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

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

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND MANUFACTURER

Eckert & Ziegler Radiopharma GmbH
Robert-Rössle-Str. 10
D-13125 Berlin
Germany

12. MARKETING AUTHORISATION NUMBER(S)

EU/1/05/322/001

13. BATCH NUMBER

BN

14. GENERAL CLASSIFICATION FOR SUPPLY

Medicinal product subject to medical prescription.

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

Justification for not including Braille accepted

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

VIAL LABEL ON PERSPEX SHIELD

1. NAME OF THE MEDICINAL PRODUCT AND ROUTE(S) OF ADMINISTRATION

Yttriga radiopharmaceutical precursor, solution.
Yttrium (^{90}Y) chloride

2. METHOD OF ADMINISTRATION

For *in vitro* radiolabelling.
Read the package leaflet before use.
NOT INTENDED FOR DIRECT APPLICATION TO PATIENTS

3. EXPIRY DATE

EXP (12h CET)

4. BATCH NUMBER

BN

5. CONTENTS BY WEIGHT, BY VOLUME OR BY UNIT

Vol.: {Z} ml
Act.: {Y}_____GBq/vial Cal.: {DD/MM/AAAA} (12h CET)

6. OTHER

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

VIAL

1. NAME OF THE MEDICINAL PRODUCT AND ROUTE(S) OF ADMINISTRATION

Yttriga solution
Yttrium (^{90}Y) chloride

2. METHOD OF ADMINISTRATION

in vitro labelling

3. EXPIRY DATE

Exp

4. BATCH NUMBER

BN

5. CONTENTS BY WEIGHT, BY VOLUME OR BY UNIT

Vol.: {Z} ml
Act.: {Y}_____GBq/vial Cal.: {DD/MM/AAAA} (12h CET)

6. OTHER

PARTICULARS TO APPEAR ON THE OUTER PACKAGING AND THE IMMEDIATE PACKAGING

TIN CAN AND LEAD POT

1. NAME OF THE MEDICINAL PRODUCT

Yttriga radiopharmaceutical precursor, solution.
Yttrium (^{90}Y) chloride

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Yttrium (^{90}Y) chloride

Act.: (Y) GBq/vial

Cal.: {DD/MM/YYYY} (12h CET)

Specific activity at calibration: (Y) GBq/vial

3. LIST OF EXCIPIENTS

Hydrochloric acid (0.04 M)

4. PHARMACEUTICAL FORM AND CONTENTS

Radiopharmaceutical precursor, solution.

1 vial
Vol.: {Z} ml

5. METHOD AND ROUTE(S) OF ADMINISTRATION

For *in vitro* radiolabelling. Read the package leaflet before use.
NOT INTENDED FOR DIRECT ADMINISTRATION TO PATIENTS

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE REACH AND SIGHT OF CHILDREN

Keep out of the reach and sight of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

The vial may contain high pressure due to radiolysis.

8. EXPIRY DATE

EXP {MM/YYYY} (12h CET)

9. SPECIAL STORAGE CONDITIONS

Store in the original package.

Storage should be in accordance with local regulations for radioactive substances.

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

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

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND MANUFACTURER

Eckert & Ziegler Radiopharma GmbH
Robert-Rössle-Str. 10
D-13125 Berlin
Germany

12. MARKETING AUTHORISATION NUMBER(S)

EU/1/05/322/002

13. BATCH NUMBER

BN

14. GENERAL CLASSIFICATION FOR SUPPLY

Medicinal product subject to medical prescription.

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

Justification for not including Braille accepted

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

VIAL LABEL ON PERSPEX SHIELD

1. NAME OF THE MEDICINAL PRODUCT AND ROUTE(S) OF ADMINISTRATION

Yttriga radiopharmaceutical precursor, solution.
Yttrium (^{90}Y) chloride

2. METHOD OF ADMINISTRATION

For *in vitro* radiolabelling.
Read the package leaflet before use.
NOT INTENDED FOR DIRECT APPLICATION TO PATIENTS

3. EXPIRY DATE

EXP (12h CET)

4. BATCH NUMBER

BN

5. CONTENTS BY WEIGHT, BY VOLUME OR BY UNIT

Vol.: {Z} ml
Act.: {Y}_____GBq/vial Cal.: {DD/MM/AAAA} (12h CET)

6. OTHER

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

VIAL

1. NAME OF THE MEDICINAL PRODUCT AND ROUTE(S) OF ADMINISTRATION

Yttriga solution
Yttrium (^{90}Y) chloride

2. METHOD OF ADMINISTRATION

in vitro labelling

3. EXPIRY DATE

Exp

4. BATCH NUMBER

BN

5. CONTENTS BY WEIGHT, BY VOLUME OR BY UNIT

Vol.: {Z} ml
Act.: {Y}_____GBq/vial Cal.: {DD/MM/AAAA} (12h CET)

6. OTHER

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

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. 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-shapped 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.

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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.