

**PARTICULARS TO APPEAR ON THE OUTER PACKAGING**

**Tin containing radioactive kit (radiolabel in lead shielding and buffer)**

**1. NAME OF THE MEDICINAL PRODUCT**

Indium (In111) Oxinate  
37 MBq/mL; Radiopharmaceutical precursor.

Indium (In-111) chloride

DRN 4908 (= Code on vial)

**2. STATEMENT OF ACTIVE SUBSTANCE(S)**

Indium (In111) Oxinate: Indium (In-111) chloride 37 MBq/mL at [YYYY-MM-DD hh:mm] h CET, Oxine  
0.025 mg  
Tris: Tris buffer 0.2 M, pH 8.0

**3. LIST OF EXCIPIENTS**

Indium (In111) Oxinate: Sodium acetate trihydrate, acetic acid anhydrous, ferric chloride hexahydrate,  
sodium chloride, hydrochloric acid and water for injections.  
Tris: Hydrochloric acid, trometamol and water for injections.

**4. PHARMACEUTICAL FORM AND CONTENTS**

The tin contains two vials:  
Indium (In111) Oxinate: Radiopharmaceutical precursor. 37 MBq/1 mL  
Tris: Solution for injection. 3 mL

**5. METHOD AND ROUTE(S) OF ADMINISTRATION**

For intravenous use after in-vitro labelling of blood cells.  
Read the package leaflet before use.

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

Keep out of the sight and reach of children.

**7. OTHER SPECIAL WARNING(S), IF NECESSARY**

First use: [YYYY-MM-DD hh:mm] h CET

**8. EXPIRY DATE**

EXP: [YYYY-MM-DD hh:mm] h CET

**9. SPECIAL STORAGE CONDITIONS**

Store below 25 °C.

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

Radioactive waste disposal should be in accordance with national regulations. After decay of radioactivity there are no special precautions for waste disposal.

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

Curium Netherlands B.V., Westerduinweg 3, 1755 LE Petten, The Netherlands

**12. MARKETING AUTHORISATION NUMBER(S)**

88/381/93-C

**13. BATCH NUMBER**

Lot: [12345]

**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

**PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING**

Lead shielding In-111 oxinate

**1. NAME OF THE MEDICINAL PRODUCT**

Indium (In111) Oxinate  
37 MBq/mL; Radiopharmaceutical precursor.

Indium (In-111) chloride

DRN 4908 (= Code on vial)

**2. STATEMENT OF ACTIVE SUBSTANCE(S)**

Indium (In-111) chloride 37 MBq/mL at [YYYY-MM-DD hh:mm] h CET, Oxine 0.025 mg

**3. LIST OF EXCIPIENTS**

Sodium acetate trihydrate, acetic acid anhydrous, ferric chloride hexahydrate, sodium chloride, hydrochloric acid and water for injections.

**4. PHARMACEUTICAL FORM AND CONTENTS**

Radiopharmaceutical precursor. 37 MBq/1 mL

**5. METHOD AND ROUTE(S) OF ADMINISTRATION**

For intravenous use after in-vitro labelling of blood cells.  
Read the package leaflet before use.

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

Keep out of the sight and reach of children.

**7. OTHER SPECIAL WARNING(S), IF NECESSARY**

First use: [YYYY-MM-DD hh:mm] h CET

**8. EXPIRY DATE**

EXP: [YYYY-MM-DD hh:mm] h CET

**9. SPECIAL STORAGE CONDITIONS**

Store below 25 °C.

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

Radioactive waste disposal should be in accordance with national regulations. After decay of radioactivity there are no special precautions for waste disposal.

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

Curium Netherlands B.V., Westerduinweg 3, 1755 LE Petten, The Netherlands

**12. MARKETING AUTHORISATION NUMBER(S)**

88/381/93-C

**13. BATCH NUMBER**

Lot [12345]

**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**

In case of radiopharmaceuticals the vial should be labelled in accordance to the article 66(3) of Directive 2001/83.

Vial label: In-111

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

DRN 4908 In-111

**2. METHOD OF ADMINISTRATION**

**3. EXPIRY DATE**

EXP: [YYYY-MM-DD hh:mm] h CET

**4. BATCH NUMBER**

Lot: [00000/000]

**5. CONTENTS BY WEIGHT, BY VOLUME OR BY UNIT**

37 MBq/1 mL  
[YYYY-MM-DD hh:mm] h CET

**6. OTHER**

Curium Netherlands B.V.



**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS**

**Vial label: Tris buffer**

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

Tris buffer 0.2 M pH 8.0  
Solution for injection

**2. METHOD OF ADMINISTRATION**

For intravenous use after in-vitro labelling of blood cells.

**3. EXPIRY DATE**

EXP [YYYY-MM-DD]

**4. BATCH NUMBER**

Lot [000000]

**5. CONTENTS BY WEIGHT, BY VOLUME OR BY UNIT**

3 mL

**6. OTHER**