

**PARTICULARS TO APPEAR ON THE OUTER PACKAGING**

**1. NAME OF THE MEDICINAL PRODUCT**

Indium (In111) Chloride  
DRN 4901 (= Code on vial)

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

Indium (In111) chloride y MBq in x mL at ART  
y MBq [YYYY-MM-DD hh:mm] h CET

**3. LIST OF EXCIPIENTS**

Also contains: hydrochloric acid and water for injections.

**4. PHARMACEUTICAL FORM AND CONTENTS**

Radiopharmaceutical precursor  
1 multidose vial of 370 MBq/ml.

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

For radiolabelling. 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**

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)**

88/380/93-C

**13. BATCH NUMBER**

Lot: [12345]

**14. GENERAL CLASSIFICATION FOR SUPPLY**

**15. INSTRUCTIONS ON USE**



**16. INFORMATION IN BRAILLE**

*[Neuplatňuje se – odůvodnění přijato]*

**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. THE NAME OR CODE OF THE MEDICINAL PRODUCT, INCLUDING THE NAME OR CHEMICAL SYMBOL OF THE RADIONUCLIDE**

DRN 4901 In-111

**2. THE AMOUNT OF RADIOACTIVITY**

y MBq/x mL  
[YYYY-MM-DD hh:mm] h CET

**3. EXPIRY DATE**

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

**4. BATCH NUMBER**

Lot: [00000/000]

**5. THE NAME OF THE MANUFACTURER**

Curium Netherlands B.V.

**6. THE INTERNATIONAL SYMBOL FOR RADIOACTIVITY**

