

## PARTICULARS TO APPEAR ON THE OUTER PACKAGING

**Tin and lead jar**

### 1. NAME OF THE MEDICINAL PRODUCT

Indium (In-111) DTPA 37 MBq/mL solution for injection  
DRN 4916 (= *Code on vial*)

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

Indium (In-111) pentetate  MBq in  mL at ART  
Pentetic acid 0.1 mg/mL

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

### 3. LIST OF EXCIPIENTS

Contains also: calcium chloride dihydrate, sodium chloride, disodium phosphate dodecahydrate, hydrochloric acid, sodium hydroxide and water for injections.

### 4. PHARMACEUTICAL FORM AND CONTENTS

1 multidose vial of 37 MBq/mL in 1 mL.  
1 multidose vial of 37 MBq/mL in 0.5 mL.  
Solution for injection.

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

For intrathecal use.  
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  
If multi-dose use is intended, each aliquot should be removed under aseptic conditions and within one working day. The vial should be stored between 2°C-8°C after removal of the first aliquot.

**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.

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

Curium Netherlands BV, Westerduinweg 3, 1755 LE Petten, The Netherlands

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

88/761/93-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 - Indium (In-111) is only intended for administration by healthcare professionals]

**17. UNIQUE IDENTIFIER – 2D BARCODE**

Not applicable.

**18. UNIQUE IDENTIFIER - HUMAN READABLE DATA**

Not applicable.

**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 4916 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**



With y = 18.5 or 37 and x, z = 0.5 or 1.0