

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

tin label and lead pot

1. NAME OF THE MEDICINAL PRODUCT

Thallous (TI201) Chloride Injection, 37 MBq/ml, solution for injection

DRN 8103 (Code of the product) Thallous (TI-201) Chloride

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Contains:

Thallous (TI-201) Chloride 37 MBq/ml,

3. LIST OF EXCIPIENTS

sodium chloride, hydrochloric acid, sodium hydroxide and water for injections.

4. PHARMACEUTICAL FORM AND CONTENTS

Solution for injection

63 MBq in 1.7 ml at ART

85 MBq in 2.3 ml at ART

213 MBq in 5.8 ml at ART

370 MBq in 10.0 ml at ART

5. METHOD AND ROUTE(S) OF ADMINISTRATION

For multi-dose use.

Intravenous 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



8. EXPIRY DATE

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

After aseptic removal of the first aliquot the product is stable for 8 hours stored at 2 °C-8 °C.

9. SPECIAL STORAGE CONDITIONS

Do not store above 25 °C.

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

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

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)

88/211/93-C

13. BATCH NUMBER

Lot:

14. GENERAL CLASSIFICATION FOR SUPPLY

Medicinal product subject to medical prescription.

15. INSTRUCTIONS ON USE**16. INFORMATION IN BRAILLE**

Nevyžaduje se – odůvodnění přijato.

17. UNIQUE IDENTIFIER – 2D BARCODE

Not applicable

18. UNIQUE IDENTIFIER – HUMAN READABLE DATA

Not applicable

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

vial

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

Thallous (Tl201) Chloride Injection, 37 MBq/ml, solution for injection

Thallous (Tl201) Chloride

8103 (Code of the product)

Intravenous use.

2. METHOD OF ADMINISTRATION

3. EXPIRY DATE

EXP:

4. BATCH NUMBER

Lot:

5. CONTENTS BY WEIGHT, BY VOLUME OR BY UNIT

63 MBq in 1.7 ml at ART

85 MBq in 2.3 ml at ART

213 MBq in 5.8 ml at ART

370 MBq in 10.0 ml at ART

6. OTHER



Curium Netherlands B.V.