PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Tin containing radio-active kit (radiolabel in lead shielding and labeling substance)

1. NAME OF THE MEDICINAL PRODUCT

Octreoscan
111 MBq/mL
Kit for radiopharmaceutical preparation
^{111}In-Pentetreotide

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Vial A (DRN 4920/A = code on vial): Indium (^{111}In) Chloride 111 MBq/ml (122 MBq/1.1ml) at ART
Vial B: Pentetreotide 10 micrograms

3. LIST OF EXCIPIENTS

Vial A: Contains also: hydrochloric acid, water for injection and ferric chloride hexahydrate.
Vial B: Contains also: sodium citrate dihydrate, citric acid monohydrate, inositol and gentisic acid.

4. PHARMACEUTICAL FORM AND CONTENTS

Kit for radiopharmaceutical preparation. The kit consists of two vials:
Vial A: Radiopharmaceutical precursor
Vial B: Powder for solution for injection

5. METHOD AND ROUTE(S) OF ADMINISTRATION

For intravenous use after reconstitution.
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 [DD MMM YYYY]
After reconstitution and labeling: expiry 6 hours

9. SPECIAL STORAGE CONDITIONS

Before and after reconstitution store below 25ºC.

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 B.V.
Westerduinweg 3
1755 LE Petten
The Netherlands

12. MARKETING AUTHORISATION NUMBER(S)

88/143/94-C

13. BATCH NUMBER

Lot [12345]

14. GENERAL CLASSIFICATION FOR SUPPLY

Medicinal product subject to medicinal prescription.

15. INSTRUCTIONS ON USE

The sterile needle included in the pack is to be used for the reconstitution.

16. INFORMATION IN BRAILLE

Nevyžaduje se - odůvodnění přijato.

Exception request submitted as OCTREOSCAN is solely hospital product, thus including the product name on label in Braille may be omitted.

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Lead pot

1. NAME OF THE MEDICINAL PRODUCT

Indium (^{111}In) Chloride
111 MBq/mL
Radiopharmaceutical precursor
(DRN 4920/A = code on vial)

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Indium (^{111}In) Chloride 111 MBq/mL (122 MBq/1.1mL) at ART

3. LIST OF EXCIPIENTS

Contains also: hydrochloric acid, water for injection and ferric chloride hexahydrate.

4. PHARMACEUTICAL FORM AND CONTENTS

Radiopharmaceutical precursor

5. METHOD AND ROUTE(S) OF ADMINISTRATION

For intravenous use after reconstitution.
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 [DD MMM YYYY hh:mm] h CET
After reconstitution and labeling: expiry 6 hours

9. SPECIAL STORAGE CONDITIONS

Before and after reconstitution store below 25ºC.

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

12. MARKETING AUTHORISATION NUMBER(S)

88/143/94-C

13. BATCH NUMBER

Lot [12345]

14. GENERAL CLASSIFICATION FOR SUPPLY

15. INSTRUCTIONS ON USE

The sterile needle included in the pack is to be used for the reconstitution.

16. INFORMATION IN BRAILLE

Nevyžaduje se - odůvodnění přijato.
Exception request submitted as OCTREOSCAN is solely hospital product, thus including the product name on label in Braille may be omitted.

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: Vial A

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

DRN 4920/A
In-111I

2. METHOD OF ADMINISTRATION

3. EXPIRY DATE

EXP [DD MMM YY] h CET

4. BATCH NUMBER

Lot [00000/000]

5. CONTENTS BY WEIGHT, BY VOLUME OR BY UNIT

122 MBq/1.1 mL (111 MBq/mL)
[YYYY-MM-DD hh:mm] h CET

6. OTHER

Curium Netherlands B.V., Petten, NL

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Vial label: Vial B

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

OctreoScan Vial B
Powder for solution for injection

2. METHOD OF ADMINISTRATION

Intravenous use after labelling with Vial A

3. EXPIRY DATE

EXP [DD MMM YYYY]
After reconstitution: expiry 6 Hours

4. BATCH NUMBER

Lot [000000]

5. CONTENTS BY WEIGHT, BY VOLUME OR BY UNIT

Pentetreotide 10 micrograms

6. OTHER

Curium Netherlands B.V.