

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Metal box and lead pot

1. NAME OF THE MEDICINAL PRODUCT

ERMM-1 111 MBq/ml suspension for local injection
Erbium (¹⁶⁹Er) citrate

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Erbium (¹⁶⁹Er) citrate 111 MBq/ml at calibration date

3. LIST OF EXCIPIENTS

Sodium chloride
Nitric acid
Sodium hydroxide
Water for injections

4. PHARMACEUTICAL FORM AND CONTENTS

Suspension for injection in multidose vial.

Vol: ml
.....MBq/vial {JJ/MM/AAAA} 12 h CET
.....111 MBq/ml {JJ/MM/AAAA} 12 h CET

5. METHOD AND ROUTE(S) OF ADMINISTRATION

For intra-articular injection
Read the package leaflet before use.

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

7. OTHER SPECIAL WARNING(S), IF NECESSARY

Radioactivity symbol
Radioactive medicine

8. EXPIRY DATE

EXP: JJ/MM/AAAA

9. SPECIAL STORAGE CONDITIONS

Do not store above 25 °C. Store in the original packaging
After first withdrawing, store in a refrigerator (2 °C - 8 °C) and use within 8 hours.

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

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

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

CIS bio international
B.P. 32
F-91192 GIF-SUR-YVETTE CEDEX

12. MARKETING AUTHORISATION NUMBER(S)

88/349/03-C

13. BATCH NUMBER

Batch N° : _____

14. GENERAL CLASSIFICATION FOR SUPPLY

Medicinal product subject to medical prescription.

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

Nevyžaduje se-odůvodnění přijato.

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Vial

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

ERMM-1 111 MBq/ml suspension for local injection
Erbium (¹⁶⁹Er) citrate

Intra-articular use

2. METHOD OF ADMINISTRATION

For intra-articular injection.

3. EXPIRY DATE

EXP: _MM/AAAA

4. BATCH NUMBER

Batch N° _____

5. CONTENTS BY WEIGHT, BY VOLUME OR BY UNIT

Vol :..... ml
.....MBq/vial {JJ/MM/AAAA} (12h CET)
.....111 MBq/ml {JJ/MM/AAAA} (12 h CET)

6. OTHER

Radioactivity symbol