

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Metal box and lead pot

1. NAME OF THE MEDICINAL PRODUCT

RE-186-MM-1
RHENIUM (¹⁸⁶Re) SULPHIDE CIS bio international 148-370 MBq/mL suspension for local injection
Colloidal rhenium (¹⁸⁶Re) sulphide

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Colloidal rhenium (¹⁸⁶Re) sulphide 148 to 370 MBq/ml at calibration date

3. LIST OF EXCIPIENTS

Ascorbic acid
Gelatin
Sodium hydroxide
Hydrochloric acid
Water for injections

4. PHARMACEUTICAL FORM AND CONTENTS

Suspension for injection in multidose vial.

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

5. METHOD AND ROUTE(S) OF ADMINISTRATION

For intra-articular injection under arthrographic guidance.
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 reach and sight 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 - 91192 GIF-SUR-YVETTE CEDEX, France

12. MARKETING AUTHORISATION NUMBER(S)

MA Nr: 88/099/01-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

Justification for not including Braille accepted

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Vial

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

RE-186-MM-1
RHENIUM (¹⁸⁶Re) SULPHIDE CIS bio international 148-370 MBq/mL suspension for local injection.
Colloidal rhenium (¹⁸⁶Re) sulphide

Intra-articular use

2. METHOD OF ADMINISTRATION

For intra-articular injection under arthrographic guidance.

3. EXPIRY DATE

EXP: _MM/AAAA

4. BATCH NUMBER

Batch N° _____

5. CONTENTS BY WEIGHT, BY VOLUME OR BY UNIT

.....MBq/vial {JJ/MM/AAAA} (12h CET)

6. OTHER

Radioactivity symbol