

LABELLING

**PARTICULARS TO APPEAR ON THE OUTER PACKAGING
OUTER CARTON TEXT**

1. NAME OF THE MEDICINAL PRODUCT

[INVENTED NAME]

20 micrograms/80 microliters solution for injection in pre-filled pen
Teriparatide

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each ml contains 250 micrograms of teriparatide.

3. LIST OF EXCIPIENTS

Glacial acetic acid, sodium acetate (anhydrous), mannitol, metacresol, water for injections. Hydrochloric acid solution and/or sodium hydroxide solution (for pH adjustment).

4. PHARMACEUTICAL FORM AND CONTENTS

Solution for injection.

1 pen of 2.4 ml solution. 3 pens of 2.4 ml solution each.

Each pen contains 28 doses of 20 micrograms (per 80 microliters).

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use. Subcutaneous 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

To open, lift here and pull.

8. EXPIRY DATE

EXP:

The pen should be discarded 28 days after the first use.

Date of first use:

9. SPECIAL STORAGE CONDITIONS

Store in refrigerator. Do not freeze.

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

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

[To be completed nationally]

12. MARKETING AUTHORISATION NUMBER(S)

[To be completed nationally]

13. BATCH NUMBER

Lot:

14. GENERAL CLASSIFICATION FOR SUPPLY

Medicinal product subject to medical prescription.

15. INSTRUCTIONS ON USE

Prepare pen for first injection, see User Manual.

16. INFORMATION IN BRAILLE

[INVENTED NAME]

17. UNIQUE IDENTIFIER – 2D BARCODE

2D barcode carrying the unique identifier included.

18. UNIQUE IDENTIFIER – HUMAN READABLE DATA

PC: {number}
SN: {number}
NN: {number}