

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Carton

1. NAME OF THE MEDICINAL PRODUCT

Depo-Provera 150 mg/mL suspension for injection
Depo-Provera 150 mg/mL suspension for injection, pre-filled syringe

medroxyprogesterone acetate

2. STATEMENT OF ACTIVE SUBSTANCE(S)

1 mL contains: Medroxyprogesterone acetate 150 mg

3. LIST OF EXCIPIENTS

Macrogol 3350, polysorbate 80, sodium chloride, preservative (metagin E218, propagin E216), hydrochloric acid or sodium hydroxide (for adjusting the pH) and water for injection.

4. PHARMACEUTICAL FORM AND CONTENTS

Suspension for injection
1 mL injection vial
10 injection vials of 3.3 mL
10 injection vials of 6.7 mL

Suspension for injection, pre-filled syringe
1 mL

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.
Intramuscular administration.

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

Shake well.

8. EXPIRY DATE

EXP:

9. SPECIAL STORAGE CONDITIONS

The injection vial must be stored standing upwards. Do not refrigerate. 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

Pfizer AB, Sollentuna, Sweden

12. MARKETING AUTHORISATION NUMBER(S)

Suspension for injection: MA number 9201
Suspension for injection, pre-filled syringe: MA number 9836

13. BATCH NUMBER

Lot:

14. GENERAL CLASSIFICATION FOR SUPPLY

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

Justification for not including Braille accepted.

17. UNIQUE IDENTIFIER – 2D BARCODE

2D barcode carrying the unique identifier included.

18. UNIQUE IDENTIFIER – HUMAN READABLE DATA

PC: {number}

SN: {number}

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

Label (pre-filled syringe/injection vial)

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IM

2. NAME OF THE MARKETING AUTHORISATION HOLDER

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EXP:

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Lot:

5. CONTENTS BY WEIGHT, BY VOLUME OR BY UNIT

1 mL

5. OTHER

Shake well