LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Outer carton

1. NAME OF THE MEDICINAL PRODUCT

JADELLE® sine inserter
2 x 75 mg implant
levonorgestrel.

2. STATEMENT OF ACTIVE SUBSTANCE(S)

1 implant contains:
Levonorgestrel. 75 mg

3. LIST OF EXCIPIENTS

polydimethylsiloxane, anhydrous colloidal silica

4. PHARMACEUTICAL FORM AND CONTENTS

2 implants
2 x 75 mg

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Subcutanoeus use.
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

Sterile.
If the inner package is open or defective, do not use the product.

8. EXPIRY DATE

To be inserted before: <MM/YYYY>

9. SPECIAL STORAGE CONDITIONS

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

Bayer Oy
Turku, Finland

12. MARKETING AUTHORISATION NUMBER(S)

MTnr 17098

13. BATCH NUMBER

Batch:

14. GENERAL CLASSIFICATION FOR SUPPLY

15. INSTRUCTIONS ON USE

Must be removed after 5 years.

16. INFORMATION IN BRAILLE

Justification for not including Braille accepted

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING

Pouch

1. NAME OF THE MEDICINAL PRODUCT

JADELLE® sine inserter
2 x 75 mg implant
levonorgestrel.

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each implant contains:
Levonorgestrel. 75 mg

3. LIST OF EXCIPIENTS

polydimethylsiloxane, anhydrous colloidal silica

4. PHARMACEUTICAL FORM AND CONTENTS

2 x 75 mg implant
2 implants

5. METHOD AND ROUTE(S) OF ADMINISTRATION

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

Sterile.
Do not use if the pouch is opened or damaged.

8. EXPIRY DATE

Must be inserted before: <MM/YYYY>

9. SPECIAL STORAGE CONDITIONS

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

Bayer Oy
Turku, Finland

12. MARKETING AUTHORISATION NUMBER(S)

MTnr 17098

13. BATCH NUMBER

Batch:

14. GENERAL CLASSIFICATION FOR SUPPLY

15. INSTRUCTIONS ON USE

Must be removed after 5 years.

16. INFORMATION IN BRAILLE

Justification for not including Braille accepted