

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

CARTON

1. NAME OF THE MEDICINAL PRODUCT

Mirena 20 micrograms/24 hours intrauterine delivery system
Levonorgestrel.

2. STATEMENT OF ACTIVE SUBSTANCE(S)

1 sterile intrauterine delivery system contains:
Levonorgestrel. 52 mg

3. LIST OF EXCIPIENTS

Constit q.s.

4. PHARMACEUTICAL FORM AND CONTENTS

1 sterile intrauterine delivery system

Nordic Article No. 01 44 53

5. METHOD AND ROUTE(S) OF ADMINISTRATION, IF NECESSARY

Instructions for use and insertion are inside the package.

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

8. EXPIRY DATE

To be inserted no later than:

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 AUTHORIZATION HOLDER

Bayer Oy,
Turku, Finland

12. MARKETING AUTHORIZATION NUMBER(S)

10212 FI

13. BATCH NUMBER

Lot:

14. GENERAL CLASSIFICATION FOR SUPPLY

15. INSTRUCTIONS FOR USE



Mirena in its actual size

Package leaflet and reminder card are handed out to the user. The user should read the package leaflet before use.

Scan the QR code for further information:

[QR code to package leaflet to be included nationally]

www.mirena.fi

16. INFORMATION IN BRAILLE

mirena

17. UNIQUE IDENTIFIER – 2D BARCODE

A 2D barcode carrying the unique identifier.

18. UNIQUE IDENTIFIERS – HUMAN READABLE DATA

PC
SN
NN

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING

1. NAME OF THE MEDICINAL PRODUCT

Mirena 20 micrograms/24 hours intrauterine delivery system

2. STATEMENT OF ACTIVE SUBSTANCE(S)

1 sterile intrauterine delivery system contains:
Levonorgestrel. 52 mg

3. LIST OF EXCIPIENTS

Constit. q.s.

4. PHARMACEUTICAL FORM AND CONTENTS

1 Intrauterine delivery system

Nordic Article No. 01 44 53

5. METHOD AND ROUTE(S) OF ADMINISTRATION, IF NECESSARY

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

8. EXPIRY DATE

To be inserted no later than:

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 AUTHORIZATION HOLDER

Bayer Oy,
Turku, Finland

12. MARKETING AUTHORIZATION NUMBER(S)

10212 FI

13. BATCH NUMBER

Lot:

14. GENERAL CLASSIFICATION FOR SUPPLY

15. INSTRUCTIONS FOR USE

To load Mirena, push the slider upwards.
This system cannot be re-loaded.
Please read the complete insertion instructions before insertion.

16. INFORMATION IN BRAILLE

17. UNIQUE IDENTIFIER – 2D BARCODE

Not relevant.

18. UNIQUE IDENTIFIERS – HUMAN READABLE DATA

Not relevant.

PARTICULARS TO APPEAR ON OTHER PACKAGING COMPONENTS:

REMINDER CARD FOR THE USER

Bring this card with you to every doctor's appointment

Mirena 20 micrograms/24 hours intrauterine delivery system
levonorgestrel.

Information on the product and its use: www.mirena.fi

Log in with the Nordic Article Number: 014453

[QR code to package leaflet to be included nationally]

www.mirena.fi

Bayer Oy, Finland

Mirena is used for prevention of pregnancy, excessive menstrual bleeding, menstrual pain, and as progestogen treatment during menopausal hormone replacement therapy.

User's name: <...>

Doctors's name and phone number: <...>

Date of insertion: <...>

Latest date of removal: <...>

Lot