

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Outer carton

1. Name of the medicinal product

[RH028 trade name]* Levonorgestrel 75 mg implant

2. Statement of active substance

Each implant contains levonorgestrel 75 mg

3. List of excipients

Dimethylsiloxane/methylvinylsiloxane copolymer core, silicone tubing, polydimethylsiloxane adhesive

4. Pharmaceutical form and contents

Sub-dermal implants.

2 x implants

5. Method and route of administration

Subcutaneous use.

Read the patient information leaflet before use.

6. Special warning that the medicinal product must be stored out of the reach and sight of children

Keep this medicine 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

EXP {MM/YYYY}

9. Special storage conditions

Do not store above 30°C.

Keep the product in the provided outer carton to protect from light.

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 supplier

Shanghai Dahua Pharmaceutical Co. Ltd.

3503 Changzheng Road

Chongming County

Shanghai

China

12. WHO Reference Number (Prequalification Programme)

RH028

13. Manufacturer's batch number

<Batch> <Lot> {number}

* Trade names are not prequalified by WHO. This is the national medicines regulatory authority's responsibility.

14. (Advice on) General classification for supply

Medicinal product subject to medical prescription.

15. Instructions on use

Must be removed after 3 years.

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING Pouch

1. Name of the medicinal product

[RH028 trade name] Levonorgestrel 75 mg implant

2. Statement of active substance

Each implant contains levonorgestrel 75 mg

3. List of excipients

Dimethylsiloxane/methylvinylsiloxane copolymer core, silicone tubing, polydimethylsiloxane adhesive

4. Pharmaceutical form and contents

Implants.
2 x implants

5. Method and route of administration

Subcutaneous use.
Read the patient information leaflet before use.

6. Special warning that the medicinal product must be stored out of the reach and sight of children

Keep this medicine 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

EXP {MM/YYYY}

9. Special storage conditions

Do not store above 30°C.
Keep the product in the provided outer carton to protect from light.

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 supplier

Shanghai Dahua Pharmaceutical Co. Ltd.
3503 Changzheng Road
Chongming County
Shanghai
China

12. WHO Reference Number (Prequalification Programme)

RH028

13. Manufacturer's batch number

<Batch> <Lot> {number}

14. (Advice on) General classification for supply

Medicinal product subject to medical prescription.

15. Instructions on use

Must be removed after 3 years.