

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Carton box

1. Name of the medicinal product

[RH071 trade name]* Ethinylestradiol/levonorgestrel 30 micrograms /150 micrograms tablets +
Placebo tablets
Ethinylestradiol/levonorgestrel

2. Statement of active substance

Each yellow tablet contains 30 micrograms ethinylestradiol and 150 micrograms levonorgestrel
and green tablets are placebo.

3. List of excipients

Contains lactose

4. Pharmaceutical form and contents

Film-coated tablets
1 × 28 tablets

5. Method and route of administration

Oral 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

8. Expiry date

EXP {MM/YYYY}

9. Special storage conditions

Do not store above 30°C.

10. Special precautions for disposal of unused medicinal products or waste materials derived from such medicinal products, if appropriate

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

11. Name and address of the supplier

Laboratorios Leon Farma SA
La Vallina s/n
Poligono Industrial Navatejera
Villaquilambre
Leon 24193
Spain

12. WHO Reference Number (Prequalification Programme)

RH071

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

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIP

PVC/PVDC-aluminium blister

1. Name of the medicinal product

[RH071 trade name] Ethinylestradiol/levonorgestrel 30 micrograms /150 micrograms tablets +
Placebo tablets
Ethinylestradiol/levonorgestrel

2. Name of the supplier

Laboratorios Leon Farma SA

3. Expiry date

EXP {MM/YYYY}

4. Manufacturer's batch number

<Batch> <Lot>{number}

5. Other