LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Carton box

1. Name of the medicinal product

[RH067 name][*]

Desogestrel /ethinylestradiol 0.15 mg/0.03 mg tablets

2. Statement of active substance

21 tablets containing 0.15 mg desogestrel and 0.03 mg ethinylestradiol

3. List of excipients

Contains lactose.

See the patient information leaflet for further information.

4. Pharmaceutical form and contents

PVC/PVDC-aluminium blister containing 21 active (white) 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 out of the reach of children.

7. Other special warning(s), if necessary

8. Expiry date

EXP {MM/YYYY}

9. Special storage conditions

Do not store above 25ºC. Store in the original package in order to protect from light.

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 24008
Spain

12. WHO Reference Number (Prequalification Programme)

RH067

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

Blister

1. Name of the medicinal product

[RH067 name]

Desogestrel /ethinylestradiol 0.15 mg/0.03 mg tablets

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