

## **LABELLING**

## **PARTICULARS TO APPEAR ON THE OUTER PACKAGING**

Carton box

### **1. Name of the medicinal product**

[RH066 trade name]\* Desogestrel /ethinylestradiol 150 micrograms /30 micrograms tablets + placebo tablets  
Desogestrel /ethinylestradiol

### **2. Statement of active substance**

Each white tablet contains 150 micrograms desogestrel and 30 micrograms ethinylestradiol and green placebo tablets.

### **3. List of excipients**

Contains lactose

### **4. Pharmaceutical form and contents**

Fim-coated tablets

1 × 28 tablets

3 × 28 tablets

6 × 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 25°C. Store in the original package in order to protect from light.

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

**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**

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

**12. WHO Reference Number (Prequalification Programme)**

RH066

**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-Alu Blister

**1. Name of the medicinal product**

[RH066 trade name] Desogestrel /ethinylestradiol 150 micrograms /30 micrograms tablets +  
placebo tablets

Desogestrel /ethinylestradiol

**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**