

## **LABELLING**

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

Carton box

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

[RH070 trade name]\* Ethinylestradiol/levonorgestrel 30 micrograms /150 micrograms tablets  
Ethinylestradiol/levonorgestrel

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

Each tablet contains 30 micrograms ethinylestradiol and 150 micrograms levonorgestrel.

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

Contains lactose

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

Fim-coated tablets  
1 × 21 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**

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\* 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)**

RH070

**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**

[RH070 trade name] Ethinylestradiol/levonorgestrel 30 micrograms /150 micrograms 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**