

## **LABELLING**

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

Carton box

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

[RH068 name]\*

Levonorgestrel 0,75 mg tablets

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

2 tablets containing 0,75 mg levonogestrel

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

Contains lactose.

See the patient information leaflet for further information.

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

PVC/PVDC-aluminium blister containing 2 (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 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 24008  
Spain

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

RH068

**13. Manufacturer's batch number**

<Batch> <Lot> {number}

**14. Instructions on use**

## **MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIP**

Blister

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

[RH068 name]

Levonorgestrel 0,75 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**