

## **LABELLING**

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

Carton label

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

[RH032 trade name]\* levonorgestrel 750 micrograms tablets  
Levonorgestrel

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

Each tablet contains 750 micrograms levonorgestrel.

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

Contains lactose monohydrate

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

Tablet  
1 x 2 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. Protect from light. Store the tablets in the blister in provided carton.

### **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**

Senador Laboratories Private Limited  
Plot 2B & 2C, Biotech Park, Phase II  
Lalgadi Malakpet, Medchal Malkajgiri,  
Hyderabad, Telangana, 500101  
India.

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

† Formerly Famy Care Ltd then Jai Pharma Ltd then Mylan Laboratories Limited.

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

RH032

**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**

Alu-PVC/PVDC blisters

**1. Name of the medicinal product**

[RH032 trade name] levonorgestrel 750 micrograms tablets  
Levonorgestrel

**2. Name of the supplier**

Senador Laboratories Private Limited

**3. Expiry date**

EXP {MM/YYYY}

**4. Manufacturer's batch number**

<Batch> <Lot> {number}

**5. Other**