

## **LABELLING**

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

Carton

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

[RH035 trade name]\* Ethinylestradiol/Levonorgestrel 30 µg/150 µg tablets  
Ethinylestradiol/levonorgestrel

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

Each tablet contains 30 µg ethinylestradiol and 150 µg levonorgestrel.

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

Contains lactose and sucrose.

See patient information leaflet for further information

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

Sugar-coated tablets

1×28 sugar-coated tablets

3×28 sugar-coated tablets

6×28 sugar-coated tablets

100×28 sugar-coated 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**

Store below 30°C. Store in the original package. Protect from light.

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

\*\*Formerly known as Mylan Laboratories Limited

**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

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

RH035

**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**

[RH035 trade name] Ethinylestradiol/Levonorgestrel 30 µg/150 µg tablets  
Ethinylestradiol/Levonorgestrel

**2. Name of the supplier**

Senador Laboratories Limited

**3. Expiry date**

EXP {MM/YYYY}

**4. Manufacturer's batch number**

<Batch> <Lot>{number}

**5. Other**