

## **LABELLING**



**PARTICULARS TO APPEAR ON THE OUTER PACKAGING**

**Carton**

**1. NAME OF THE MEDICINAL PRODUCT**

[RH057 trade name]\*

**2. STATEMENT OF ACTIVE SUBSTANCE**

Each tablet contains levonorgestrel 30 µg

**3. LIST OF EXCIPIENTS**

Contains lactose. See patient information leaflet for further information.

**4. PHARMACEUTICAL FORM AND CONTENTS**

28 film-coated tablets

35 film-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 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 tablets in blisters in the provided carton.

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\* Trade names are not prequalified by WHO. This is the national medicines regulatory authority's responsibility. Throughout this WHOPAR the proprietary name is given as an example only.

**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, India, 500101

**12. WHO REFERENCE NUMBER (PREQUALIFICATION PROGRAMME)**

RH057

**13. MANUFACTURER'S BATCH NUMBER**

<Batch> <Lot> <BN> {number}

**14. (Advice on) GENERAL CLASSIFICATION FOR SUPPLY**

Medicinal product subject to medical prescription.

**15. INSTRUCTIONS ON USE**

<b>MINIMUM PARTICULARS TO APPEAR ON BLISTERS</b>
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<b>1. NAME OF THE MEDICINAL PRODUCT</b>
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[RH057 trade name]

<b>2. NAME OF THE SUPPLIER</b>
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Senador Laboratories Private Limited

<b>3. EXPIRY DATE</b>
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EXP {MM/YYYY}

<b>4. BATCH NUMBER</b>
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<Batch> <Lot> <BN> {number}