## **LABELLING**

#### PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Carton

#### 1. Name of the medicinal product

[RH031 trade name]\* Levonorgestrel 1.5 mg tablets Levonorgestrel

#### 2. Statement of active substance

Each tablet contains 1.5 mg levonorgestrel

#### 3. List of excipients

Contains lactose

#### 4. Pharmaceutical form and contents

**Tablet** 

1 x 1 tablet

#### 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 tablet 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

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

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## 12. WHO Reference Number (Prequalification Programme)

RH031

## 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

Aluminium blister

## 1. Name of the medicinal product

[RH031 trade name] Levonorgestrel 1.5 mg 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