## LABELLING

### PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Carton

#### 1. Name of the medicinal product

[RH065 trade name]<sup>\*</sup> levonorgestrel 1.5mg tablets Levonorgestrel

#### 2. Statement of active substance

Each tablet contains 1.5mg Levonorgestrel

#### 3. List of excipients

The tablet contains lactose monohydrate See the patient information leaflet for further information

#### 4. Pharmaceutical form and contents

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 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  $30^{\circ}$ C. Store tablet in the blister in the provided carton in order to protect from light.

## **10.** Special precautions for disposal of unused medicinal products or waste materials derived from such medicinal products, if appropriate

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

#### 11. Name and address of the supplier

HLL Lifecare Limited (A Government of India Enterprise) Unipill Block Kanagala Belagavi (District) Karnataka India–591225

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

RH065

#### 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 BLISTER

#### 1. Name of the medicinal product

[RH065 trade name] levonorgestrel 1.5mg tablets Levonorgestrel

#### 2. Name of the supplier

HLL Lifecare Limited

### 3. Expiry date

EXP {MM/YYYY}

## 4. Manufacturer's batch number

<Batch><Lot>{number}

#### 5. Other