

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Carton

1. Name of the medicinal product

[RH065 trade name]* levonorgestrel 1.5 mg tablets

Levonorgestrel

2. Statement of active substance

Each tablet contains 1.5 mg Levonorgestrel

3. List of excipients

The tablet contains lactose monohydrate

See the patient information leaflet for further information

4. Pharmaceutical form and contents

Tablet

1 × 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. 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

* 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{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 1.5 mg tablets

Levonorgestrel

2. Name of the supplier

HLL Lifecare Limited

3. Expiry date

EXP {MM/YYYY}

4. Manufacturer's batch number

Batch{number}

5. Other