

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Carton

1. Name of the medicinal product

[RH046 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 monohydrate

4. Pharmaceutical form and contents

Tablet

1 x 1 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

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

Cipla Ltd.

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

Cipla House
Peninsula Business Park
Ganpatrao Kadam Marg
Lower Parel
Mumbai: 400013
India
Tel.: + 91 22 4191 6000
Fax : + 91 22 4191 6120
E-mail: globalra@cipla.com

12. WHO Reference Number (Prequalification Programme)

RH046

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

Blister (Clear PVC/PE/PVDC-Alu blister)

1. Name of the medicinal product

[RH046 trade name] levonorgestrel 1.5 mg tablets

Levonorgestrel

2. Name of the supplier

Cipla Ltd.

3. Expiry date

EXP {MM/YYYY}

4. Manufacturer's batch number

<Batch> <Lot>{number}

5. Other