

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Carton

- 1. Name of the medicinal product**
[RH031 trade name]* Levonorgestrel 1.5 mg Tablet
- 2. Statement of active substance**
Each tablet contains 1.5 mg Levonorgestrel
- 3. List of excipients**
The tablet also contains lactose monohydrate.
- 4. Pharmaceutical form and contents**
Tablet
1 x 1 tablet
- 5. Method and route of administration**
Oral use.
Read the package 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**
Mylan Laboratories Limited
Plot No. 564/A/22,
Road No. 92 Jubilee Hills
Hyderabad, Telangana – 500096, India
Email: Imtiyaz.basade@viatris.com
- 12. WHO Reference Number (Prequalification Programme)**
RH031
- 13. Manufacturer's batch number**
<Batch> <Lot> {number}
- 14. General classification for supply**
Medicinal product subject to medical prescription

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

[†]Formerly Famy Care Ltd then Jai Pharma Ltd

15. Instructions on use

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIP

Blister

1. Name of the medicinal product

[RH031 trade name]

Levonorgestrel 1.5 mg Tablet

2. Name of the supplier

Mylan Laboratories Limited

3. Expiry date

EXP {MM/YYYY}

4. Manufacturer's batch number

<Batch> <Lot>{number}

5. Other