LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Outer carton

1. Name of the medicinal product

[RH013 trade name][*]

Ethinylestradiol 30 micrograms and levonorgestrel 150 micrograms tablets

2. Statement of active substance

Each tablet contains 30 micrograms ethinylestradiol and 150 micrograms levonorgestrel

3. List of excipients

Contains lactose and sucrose.

See patient information leaflet for further information.

4. Pharmaceutical form and contents

Tablets

1x21 coated tablets

3x21 coated tablets

6x21 coated tablets

13x21 coated tablets

100x21 coated 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 reach and sight of children.

7. Other special warning(s), if necessary

8. Expiry date

EXP {MM/YYYY}

[*] Trade names are not prequalified by WHO. This is the national medicines regulatory authority's responsibility.
[1]Formerly known as Mylan Laboratories Limited.
[2] Mylan Laboratories Limited formerly known as Famy Care Ltd

9. Special storage conditions

Store below 30°C. Store in the original package.

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 No.564/A/22, Road No.92,
Jubilee Hills
Hyderabad, Telangana – 500096,
India

12. WHO Reference Number (Prequalification Programme)

RH013

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
PVC/PVDC-Alu blisters

1. Name of the medicinal product

[RH013 trade name][†]

Ethinylestradiol 30 micrograms and levonorgestrel 150 micrograms tablets

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

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