

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Blister carton

1. Name of the medicinal product

[RH038 trade name]* 30µg ethinylestradiol and 150µg levonorgestrel tablets

2. Statement of active substance

Each white tablet contains 30µg ethinylestradiol and 150µg levonorgestrel.

The brown tablets are hormone free.

3. List of excipients

Active tablet:

Contains lactose and sucrose.

Hormone free tablet:

Contains methylparaben, propylparaben and sucrose.

See the patient information leaflet for further information.

4. Pharmaceutical form and contents

Coated tablets

1 x 28 coated tablets

3 x 28 coated tablets

6 x 28 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 out of the sight and reach 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.

[#] Formerly known as 'Mylan Laboratories Limited'

9. Special storage conditions

Store below 30°C. Protect from light.

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 2B & 2C, Biotech Park, Phase II,
Lalgadi Malakpet, Medchal Malkajgiri,
Hyderabad, Telangana,
India, 500101

12. WHO Reference Number (Prequalification Programme)

RH038

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

1. Name of the medicinal product

[RH038 trade name] 30µg ethinylestradiol and 150µg levonorgestrel tablets
ethinylestradiol and levonorgestrel

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