

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Carton

1. Name of the medicinal product

[RH108 trade name]* 30mcg ethinylestradiol and 150mcg levonorgestrel tablets
Ethinylestradiol/levonorgestrel

2. Statement of active substance

Each yellow tablet contains 30mcg ethinylestradiol and 150mcg levonorgestrel.
The dark red tablets are hormone free.

3. List of excipients

Active tablet
Contains lactose, sucrose and a small amount of lecithin (soya)
See the patient information leaflet for further information.

4. Pharmaceutical form and contents

Coated tablets
1 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 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. Avoid excursions above 30°C. Protect from moisture.

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

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

Renata PLC
Plot-1
Section 7
Milk Vita Road
Mirpur Dhaka-1216
Bangladesh

12. WHO Reference Number (Prequalification Programme)

RH108

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

[RH108 trade name] 30mcg ethinylestradiol and 150mcg levonorgestrel tablets
ethinylestradiol and levonorgestrel

2. Name of the supplier

Renata PLC

3. Expiry date

EXP{MM/YYYY}

4. Manufacturer's batch number

<Batch> <Lot>{number}

5. Other