

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Carton

1. Name of the medicinal product

[RH093 trade name]* Ethinylestradiol/levonorgestrel 30 µg /150 µg sugar-coated tablets
+ placebo film-coated tablets

Ethinylestradiol/levonorgestrel

2. Statement of active substance

Each yellow tablets contains 30 µg ethinylestradiol and 150 µg levonorgestrel.

The white tablets are placebos.

3. List of excipients

Contains lactose monohydrate, sucrose and soya lecithin

4. Pharmaceutical form and contents

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.

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 Limited

Section 7

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

Milk Vita Road
Mirpur Dhaka-1216
Bangladesh

12. WHO Reference Number (Prequalification Programme)

RH093

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 blister card

1. Name of the medicinal product

[RH093 trade name] Ethinylestradiol/levonorgestrel 30 µg /150 µg sugar-coated tablets + placebo film-coated tablets

Ethinylestradiol/levonorgestrel

2. Name of the supplier

Renata Limited

3. Expiry date

EXP {MM/YYYY}

4. Manufacturer's batch number

<Batch> <Lot>{number}

5. Other