

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Blister label

1. NAME OF THE MEDICINAL PRODUCT

[RH013 trade name]¹

2. STATEMENT OF ACTIVE SUBSTANCE

Each tablet contains 30µg ethinylestradiol and 150µg levonorgestrel

3. LIST OF EXCIPIENTS

Contains lactose and sucrose. See patient information leaflet for further information.

4. PHARMACEUTICAL FORM AND CONTENTS

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 out of the reach and sight of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

8. EXPIRY DATE

¹Trade names are not prequalified by WHO. This is the national medicines regulatory agency's responsibility.

EXP {MM/YYYY}

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

Mylan Laboratories 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> <BN> {number}

MINIMUM PARTICULARS TO APPEAR ON BLISTER

1. NAME OF THE MEDICINAL PRODUCT

[RH013 trade name]

2. NAME OF THE SUPPLIER

Mylan Laboratories Limited

3. EXPIRY DATE

EXP {MM/YYYY}

4. BATCH NUMBER

<Batch> <Lot> <BN> {number}