Ethinylestradiol/levonorgestrel 30µg/150µg tablets (Mylan Laboratories Limited), RH038

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Blister label

1. NAME OF THE MEDICINAL PRODUCT

Zinnia F^*

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. See patient information leaflet for further information.

Hormone free tablet:

Contains methylparaben, propylparaben and sucrose. See patient information leaflet for further information.

4. PHARMACEUTICAL FORM AND CONTENTS

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 SIGHT AND REACH OF CHILDREN

Keep out of the sight and reach of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

^{*} Trade names are not prequalified by WHO. This is the national medicines regulatory authority's (NMRA) responsibility. Throughout this WHOPAR the proprietary name is given as an example only.

8. EXPIRY DATE

EXP {MM/YYYY}

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

Mylan Laboratories Limited Plot No.564/A/22, Road No.92, Jubilee Hills Hyderabad, Telangana – 500033, India

12. WHO REFERENCE NUMBER (PREQUALIFICATION PROGRAMME)

RH038

13. MANUFACTURER'S BATCH NUMBER

<Batch> {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 STRIPS

1. NAME OF THE MEDICINAL PRODUCT

Zinnia F

2. NAME OF THE SUPPLIER

Mylan Laboratories Limited GUJ/DRUGS/G-1072

3. EXPIRY DATE

EXP {MM/YYYY}

4. BATCH NUMBER

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