WHOPAR part 5

Updated: February 2017

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Blister label

1. NAME OF THE MEDICINAL PRODUCT

Zinnia P *

2. STATEMENT OF ACTIVE SUBSTANCE

Each white tablet contains 30µg ethinylestradiol and 150µg levonorgestrel. The yellow tablets do not contain active substances

3. LIST OF EXCIPIENTS

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

4. PHARMACEUTICAL FORM AND CONTENTS

1x28 coated tablets

3x28 coated tablets

6x28 coated tablets

100x28 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

8. EXPIRY DATE

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^{*}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.

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EXP {MM/YYYY}

9. SPECIAL STORAGE CONDITIONS

Store below30°C. Store in the original package. 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)

RH035

13. MANUFACTURER'S BATCH NUMBER

<Batch> {number}

14. (ADVICE ON) GENERAL CLASSIFICATION FOR SUPPLY

Medicinal product subject to medical prescription.

15. INSTRUCTIONS ON USE

Updated: February 2017

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

1. NAME OF THE MEDICINAL PRODUCT

Zinnia P

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}