LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING:

Aluminium push-through foil and PVC/PVDC film blister packaging. *

**: Information regarding the package sizes in the labelling of each Member State: The package sizes included in each labelling will be the approved for the reference product in the each relevant Member State*

1. NAME OF THE MEDICINAL PRODUCT

<invented name> 0.150 mg/0.030 mg film-coated tablets

Desogestrel / Ethinylestradiol

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each film-coated tablet contains 0.150 mg of desogestrel and 0.030 mg of ethinylestradiol

3. LIST OF EXCIPIENTS

Contains lactose monohydrate and soybean oil. See leaflet for further information.

4. PHARMACEUTICAL FORM AND CONTENTS

Film-coated tablets.

1 x 21 film-coated tablets
3 x 21 film-coated tablets
6 x 21 film-coated tablets

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Oral use
Read the package 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

EXP {MM/YYYY}

9. SPECIAL STORAGE CONDITIONS

Do not store above 30ºC. Store in the original package in order to 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 MARKETING AUTHORISATION HOLDER

[To be completed nationally]

12. MARKETING AUTHORISATION NUMBER(S)

[To be completed nationally]

13. BATCH NUMBER

Batch:

14. GENERAL CLASSIFICATION FOR SUPPLY

[To be completed nationally]

15. INSTRUCTIONS ON USE

[To be completed nationally]

16. INFORMATION IN BRAILLE

<invented name> film-coated tablets

17. UNIQUE IDENTIFIER – 2D BARCODE

<2D barcode carrying the unique identifier included.>

18. UNIQUE IDENTIFIER – HUMAN READABLE DATA

PC: {number}
SN: {number}
NN: {number}

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

Aluminium push-through foil and PVC/PVDC film blister packaging.

1. NAME OF THE MEDICINAL PRODUCT

<invented name> 0.150 mg / 0.030 mg film-coated tablets
Desogestrel/Ethinylestradiol

2. NAME OF THE MARKETING AUTHORISATION HOLDER

[To be completed nationally]

3. EXPIRY DATE

EXP {MM/YYYY}

4. BATCH NUMBER

Batch:

5. OTHER

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