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> 0.03 mg/3 mg film-coated tablets

Ethinylestradiol / Drospirenone

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each yellow film-coated tablet contains 0.03 mg of ethinylestradiol and 3 mg of drospirenone

3. LIST OF EXCIPIENTS

Contains lactose monohydrate.
See leaflet for further information.

4. PHARMACEUTICAL FORM AND CONTENTS

Film-coated tablet.

21 film-coated tablets
2 x 21 film-coated tablets
3 x 21 film-coated tablets
6 x 21 film-coated tablets
13 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 REACH AND SIGHT 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

Store below 30ºC.

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 IDENTIFIERS - 2D BARCODE

2D barcode with a unique identifier.

For OTC products:
Not applicable.

18. UNIQUE IDENTIFIERS – DATA LEGIBLE WITH THE EYE

PC:
SN:
NN:

For OTC products:
Not applicable.

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> 0.03 mg / 3 mg film-coated tablets
Ethinylestradiol /Drospirenone

2. NAME OF THE MARKETING AUTHORISATION HOLDER

[To be completed nationally]

3. EXPIRY DATE

<EXP {MM/YYYY}

4. BATCH NUMBER

Batch :

5. OTHER

The days of the week of the pills, with arrow marks between the pill nests:
mon->tue->wen->thu->fri->sa->sun-> mon->tue->wen->thu->fri->sa->sun-> mon->tue->wen->thu->fri- >sa->sun

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