

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> 150 micrograms/20 micrograms film-coated tablets

Desogestrel / Ethinylestradiol

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each film-coated tablet contains 150 micrograms of desogestrel and 20 micrograms 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 this medicine 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 30°C. 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> 150 micrograms/20 micrograms film-coated tablets

17. UNIQUE IDENTIFIER – 2D BARCODE

<2D barcode carrying the unique identifier included.>

18. UNIQUE IDENTIFIER – HUMAN READABLE DATA

PC:
SN:
NN:

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> 150 micrograms/20 micrograms 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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PARTICULARS TO APPEAR ON THE OUTER PACKAGING:

Blister holder

1. NAME OF THE MEDICINAL PRODUCT

<invented name> 150 micrograms/20 micrograms film-coated tablets

Desogestrel / Ethinylestradiol

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each film-coated tablet contains 150 micrograms of desogestrel and 20 micrograms of ethinylestradiol.

3. LIST OF EXCIPIENTS

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

4. PHARMACEUTICAL FORM AND CONTENTS

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 this medicine out of the sight and reach of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

8. EXPIRY DATE

9. SPECIAL STORAGE CONDITIONS

Do not store above 30°C. 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

14. GENERAL CLASSIFICATION FOR SUPPLY

<[To be completed nationally]>

15. INSTRUCTIONS ON USE

<[To be completed nationally]>

16. INFORMATION IN BRAILLE

<invented name> 150 mcg/20 mcg

17. UNIQUE IDENTIFIER – 2D BARCODE

<[In case no outer packaging is used:]>

<2D barcode carrying the unique identifier included.>

18. UNIQUE IDENTIFIER – HUMAN READABLE DATA

<[In case no outer packaging is used:]>

PC: {number}

SN: {number}

NN: {number}

19. OTHER INFORMATION ESSENTIAL FOR CORRECT USE AND ADMINISTRATION

What to do if you forget to take <invented name>150 micrograms/20 micrograms film-coated tablets:
Less than 12 hours late:

- Take the missed tablet as soon as you remember and take the next tablet at the usual time.

More than 12 hours late:

- One tablet forgotten in week 1 or week 2: Take the forgotten tablet as soon as you remember, even if it means that you have to take 2 tablets at the same time. Continue taking the tablets at the usual time and if you are in week 1 use extra precautions for the next 7 days (e.g. condoms).
- One tablet forgotten in week 3: see leaflet.

For further information read the leaflet or consult a healthcare professional.