

LABELLING

PARTICULARS TO APPEARS ON THE OUTER PACKAGING AND THE IMMEDIATE PACKAGING

{ Folded carton box }

1. NAME OF THE MEDICINAL PRODUCT

<INVENTED NAME>, 150 micrograms/30 micrograms, tablets

Desogestrel/Ethinylestradiol

2. STATEMENT OF ACTIVE SUBSTANCES

Each tablet contains:

Desogestrel 150 micrograms

Ethinylestradiol 30 micrograms

3. LIST OF EXCIPIENTS

Also contains lactose monohydrate. See the package leaflet for further information.

4. PHARMACEUTICAL FORM AND CONTENTS

21 tablets

63 tablets

5. METHOD AND ROUTE OF ADMINISTRATION

For oral use.

Read the package leaflet before use.

6. SPECIAL WARNING I 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, IF NECESSARY

8. EXPIRY DATE

Exp.:

9. SPECIAL STORAGE CONDITIONS

Do not store above 25°C

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCT, IF APPROPRIATE

"To be completed nationally"

11. NAME AND ADDRESS OF THE MARKETING AUTHORIZATION HOLDER

<[To be completed nationally]>

12. MARKETING AUTHORISATION NUMBER

<[To be completed nationally]>

13. BATCH NUMBER

Batch:

14. GENERAL CLASSIFICATION FOR SUPPLY

15. INSTRUCTION ON USE

16. INFORMATION IN BRAILLE

<[Invented name]>

MINIMUM PARTICULARS TO APPEAR ON BLISTER

{Blister}

1. NAME OF THE MEDICINAL PRODUCT

<INVENTED NAME> 150 µg/30 µg, tablets
Desogestrel/Ethinylestradiol

2. NAME OF THE MARKETING AUTHORIZATION HOLDER

<[To be completed nationally]>

3. EXPIRY DATE

Exp.:

4. BATCH NUMBER

Batch:

5. OTHER

Start
Mon-Tue-Wed-Thu-Fri-Sat-Sun