

Sandoz	Business use only	Page 1 of 4
1.3.1 spc-label-pl - common-outer - 3,940 (DK/H/2442/001/IB/002 – Response on DAY20 comments)		20170817
DESOGESTREL 75 MCG FILM-COATED TABLET		722-2156.00

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING AND THE IMMEDIATE PACKAGING

CARTON (FOR BLISTERS)

1. NAME OF THE MEDICINAL PRODUCT

[Nationally completed name] 75 microgram film-coated tablets

Formatiert: Hervorheben

desogestrel

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each film-coated tablet contains 75 microgram desogestrel

3. LIST OF EXCIPIENTS

Contains lactose monohydrate and soya-bean oil.
See leaflet for further information

Formatiert: Schriftart: 11 Pt.

4. PHARMACEUTICAL FORM AND CONTENTS

Film-coated tablet.

Formatiert: Nicht Hervorheben

1x28 film-coated tablets
3x28 film-coated tablets
6x28 film-coated tablets
13x28 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

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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

9. SPECIAL STORAGE CONDITIONS

Do not store above 30°C. Store in the original package in order to protect from light.

Formatiert: Schriftart: 11 Pt., Schriftfarbe: Automatisch

Formatiert: Schriftart: 11 Pt.

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]

Formatiert: Hervorheben

12. MARKETING AUTHORISATION NUMBER(S)

[To be completed nationally]

Formatiert: Hervorheben

13. BATCH NUMBER

Lot

14. GENERAL CLASSIFICATION FOR SUPPLY

[To be completed nationally]

Formatiert: Hervorheben

15. INSTRUCTIONS ON USE

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16. INFORMATION IN BRAILLE

To be completed nationally

Formatiert: Hervorheben

17. UNIQUE IDENTIFIER – 2D BARCODE

2D barcode carrying the unique identifier included.

To be completed nationally

18. UNIQUE IDENTIFIER - HUMAN READABLE DATA

PC: {number}

SN: {number}

NN: {number}

Formatiert: Nicht Hervorheben

Formatiert: Nicht Hervorheben

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MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS
{Blister}

1. NAME OF THE MEDICINAL PRODUCT

Nationally completed name 75 microgram film-coated tablets

desogestrel

Formatiert: Schriftart: 11 Pt., Hervorheben

Formatiert: Schriftart: 11 Pt.

2. NAME OF THE MARKETING AUTHORISATION HOLDER

To be completed nationally

Formatiert: Hervorheben

3. EXPIRY DATE

EXP

4. BATCH NUMBER

Lot

5. OTHER

(The blister contains the week days and arrows printed; arrows are printed on both sides for clear directions)

MON TUE WED THR FRI SAT SUN
MON TUE WED THR FRI SAT SUN
MON TUE WED THR FRI SAT SUN
MON TUE WED THR FRI SAT SUN

Formatiert: Hervorheben