

## 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/20 micrograms, tablets

Desogestrel/ Ethinylestradiol

#### **2. STATEMENT OF ACTIVE SUBSTANCES**

Each tablet contains:

Desogestrel ..... 150 micrograms

Ethinylestradiol ..... 20 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**

Not applicable.

#### **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 AUTORISATION NUMBER**

<[To be completed nationally]>

**13. BATCH NUMBER**

Batch:

**14. GENERAL CLASSIFICATION FOR SUPPLY**

<[To be completed nationally]>

**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/20 µg, tablets

Desogestrel/Ethinylestradiol

**11. 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