

## 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> 150 micrograms/30 micrograms film-coated tablets

Desogestrel / Ethinylestradiol

### **2. STATEMENT OF ACTIVE SUBSTANCE(S)**

Each film-coated tablet contains 150 micrograms of desogestrel and 30 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 REACH AND SIGHT 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/30 micrograms film-coated tablets

**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/30 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**

MON TUE WED THU FRI SAT SUN  
MON TUE WED THU FRI SAT SUN  
MON TUE WED THU FRI SAT SUN

**MINIMUM PARTICULARS TO APPEAR ON BLISTER HOLDER**

**1. NAME OF THE MEDICINAL PRODUCT**

<invented name>150 micrograms/30 micrograms film-coated tablets  
Desogestrel/Ethinylestradiol

**2. NAME OF THE MARKETING AUTHORISATION HOLDER**

Actavis logo

**3. EXPIRY DATE**

**4. BATCH NUMBER**

**5. OTHER**

What to do if you forget to take <invented name>150 micrograms/30 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.