

## **LABELLING**

## **PARTICULARS TO APPEAR ON THE OUTER PACKAGING**

**Outer carton**

### **1. NAME OF THE MEDICINAL PRODUCT**

<INVENTED NAME> 750 microgram 0.75 mg tablets

Levonorgestrel

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

Each tablet contains 750 microgram 0.75 mg of levonorgestrel .

### **3. LIST OF EXCIPIENTS**

Contains lactose monohydrate. See leaflet for further information.

### **4. PHARMACEUTICAL FORM AND CONTENTS**

2 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 out of the sight and reach of children.

### **7. OTHER SPECIAL WARNING(S), IF NECESSARY**

If you have used certain other medicines in the last 4 weeks, in particular treatment for epilepsy, tuberculosis, for HIV infection or herbal medicines containing St. John's wort (see leaflet), <Invented name> may work less effectively. If you use these medicines, take 4 tablets of < Invented name>. If you are unsure or to ask for an alternative treatment speak to your doctor or pharmacist before using < Invented name>.

### **8. EXPIRY DATE**

EXP

**9. SPECIAL STORAGE CONDITIONS**

**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**

LOT

**14. GENERAL CLASSIFICATION FOR SUPPLY**

<[To be completed nationally]>

**Only for UK**

POM

**15. INSTRUCTIONS ON USE**

**Only for OTC products** (to be included or not, depending on the countries in the national step of the procedure)

Indication:

Emergency contraception within 72 hours of unprotected sexual intercourse or failure of a contraception method .

Recommended dose:

Take two tablets at the same time as soon as possible, preferably within 12 hours and no later than 72 hours after you have had unprotected sex.

**16. INFORMATION IN BRAILLE**

<INVENTED NAME>

**17. UNIQUE IDENTIFIER – 2D BARCODE**

*For Rx products:*

2D barcode carrying the unique identifier included.

*For OTC products:*

Not applicable.

**18. UNIQUE IDENTIFIER – HUMAN READABLE DATA**

*For Rx products:*

PC:

SN:

NN:

*For OTC products:*

Not applicable.

**MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS**

**PVC/PVDC/Aluminium blister**

**1. NAME OF THE MEDICINAL PRODUCT**

<INVENTED NAME> 750 microgram 0.75 mg tablets

Levonorgestrel

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

<[To be completed nationally]>

**3. EXPIRY DATE**

EXP

**4. BATCH NUMBER**

LOT

**5. OTHER**