

## **LABELLING**

**PARTICULARS TO APPEAR ON THE OUTER PACKAGING**

Carton box\*

\*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> 2 mg / 1 mg, film-coated tablets

Estradiol valerate + Dienogest

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

Each film-coated tablet contains 1 mg estradiol valerate (equivalent to 0.764 mg estradiol) / 2 mg dienogest-

**3. LIST OF EXCIPIENTS**

Also contains lactose monohydrate  
See leaflet for further information.

**4. PHARMACEUTICAL FORM AND CONTENTS**

Film-coated tablet

28 film-coated tablets  
3x28 film-coated tablets  
6x28 film-coated tablets

**5. METHOD AND ROUTE(S) OF ADMINISTRATION**

Read the package leaflet before use.  
Oral 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**

Not for use as a contraceptive

**8. EXPIRY DATE**

Exp

**9. SPECIAL STORAGE CONDITIONS**

Store in the original package 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**

Lot:

**14. GENERAL CLASSIFICATION FOR SUPPLY**

Medicinal product subject to medical prescription.

**15. INSTRUCTIONS ON USE**

**16. INFORMATION IN BRAILLE**

<INVENTED NAME> film-coated tablet

**17. UNIQUE IDENTIFIERS - 2D BARCODE**

2D barcode with a unique identifier.

**18. UNIQUE IDENTIFIERS - DATA LEGIBLE WITH THE EYE**

PC:

SN:

NN:

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

**PVC/PVDC/Aluminium blister**

**1. NAME OF THE MEDICINAL PRODUCT**

<INVENTED NAME> 2 mg/ 1 mg, film-coated tablets

Estradiol valerate + Dienogest

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

<[To be completed nationally]>

**3. EXPIRY DATE**

Exp

**4. BATCH NUMBER**

Lot

**5. OTHER**

The order numbers of the pills, with arrow marks between the pill nests:

mon.->tue.->wen.->thu.->fri.->sa.->sun.-> mon.->tue.->wen.->thu.->fri.->sa.->sun.-> mon.->tue.->wen.->thu.->fri.->sa.->sun

**MINIMUM PARTICULARS TO APPEAR ON BLISTER HOLDER (if applicable)**

**1. NAME OF THE MEDICINAL PRODUCT**

<INVENTED NAME> film-coated tablets

Estradiol valerate / dienogest

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

<[To be completed nationally]>

**3. EXPIRY DATE**

**4. BATCH NUMBER**

**5. OTHER**

<[To be completed nationally]>