

**PARTICULARS TO APPEAR ON THE OUTER PACKAGING**

**Outer carton for blister**

**1. NAME OF THE MEDICINAL PRODUCT**

/.../ 10 mg soft capsules  
/.../ 20 mg soft capsules  
isotretinoin

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

Each capsule contains 10 mg isotretinoin.  
Each capsule contains 20 mg isotretinoin.

**3. LIST OF EXCIPIENTS**

Contains ponceau 4R (E 124), sorbitol and soya-bean oil. See leaflet for further information.

**4. PHARMACEUTICAL FORM AND CONTENTS**

10 soft capsules  
20 soft capsules  
30 soft capsules  
60 soft capsules  
90 soft capsules  
100 soft capsules

**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**

**WARNING**

**CAN SERIOUSLY HARM AN UNBORN BABY**

Women must use effective contraception

Do not use if you are pregnant or think you may be pregnant

**8. EXPIRY DATE**

EXP

**9. SPECIAL STORAGE CONDITIONS**

Keep the blister in the outer carton 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**

Lot

**14. GENERAL CLASSIFICATION FOR SUPPLY**

Medicinal product subject to medical prescription.

**15. INSTRUCTIONS ON USE**

**16. INFORMATION IN BRAILLE**

/.../ 10 mg

/.../ 20 mg

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

2D barcode carrying the unique identifier included.

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

PC  
SN  
NN