

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