

## **LABELLING**



THIS DOCUMENT CONTAINS TRADE SECRETS, AND/OR COMMERCIAL OR FINANCIAL INFORMATION, PRIVILEGED OR CONFIDENTIAL, DELIVERED IN CONFIDENCE AND RELIANCE THAT SUCH INFORMATION WILL NOT BE COPIED OR MADE AVAILABLE TO ANY THIRD PARTY WITHOUT THE WRITTEN CONSENT OF LEO PHARMA A/S

**PARTICULARS TO APPEAR ON THE OUTER PACKAGING AND THE IMMEDIATE PACKAGING**

**CARTON (5 g, 15 g, 30 g and 60 g) AND LABEL (15 g, 30 g and 60 g)**

**1. NAME OF THE MEDICINAL PRODUCT**

Fucicort® Lipid 20 mg/g + 1 mg/g cream

fusidic acid/betamethasone

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

Active substances:

fusidic acid 20 mg/g

betamethasone (as valerate) 1 mg/g

**3. LIST OF EXCIPIENTS**

Other ingredients:

Steareth-21, cetostearyl alcohol, white soft paraffin, liquid paraffin, hypromellose, citric acid monohydrate, methyl parahydroxybenzoate (E218), propyl parahydroxybenzoate (E216), potassium sorbate, all-rac- $\alpha$ -tocopherol and purified water.

**4. PHARMACEUTICAL FORM AND CONTENTS**

Cream

5 g

15 g

30 g

60 g

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

Read the package leaflet before use.

Cutaneous use

For external use only

**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**



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**8. EXPIRY DATE**

EXP

Discard the tube 3 months after first opening.

**9. SPECIAL STORAGE CONDITIONS**

Do not store above 30°C

**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]>

{Name and Address}

<{tel}>

<{fax}>

<{e-mail}>

**12. MARKETING AUTHORISATION NUMBER(S)**

<[To be completed nationally]>

**13. BATCH NUMBER**

Lot

**14. GENERAL CLASSIFICATION FOR SUPPLY**

<[To be completed nationally]>

**15. INSTRUCTIONS ON USE**

**16. INFORMATION IN BRAILLE**

Carton text: fucibet lipid cream



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

Carton text:

2D barcode carrying the unique identifier included.

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

Carton text:

PC: {number}

SN: {number}

NN: {number}



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

**LABEL 5 g**

**1. NAME OF THE MEDICINAL PRODUCT**

Fucicort® Lipid 20 mg/g + 1 mg/g cream

fusidic acid/betamethasone

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

<[To be completed nationally]>

{Name and Address}

<{tel}>

<{fax}>

<{e-mail}>

**3. EXPIRY DATE**

EXP

Discard the tube 3 months after first opening.

**4. BATCH NUMBER**

Lot

**5. OTHER**

