

## **PACKAGE LEAFLET**



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## Package leaflet: Information for the user

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

Fusidic acid/betamethasone

**Read all of this leaflet carefully before you start using this medicine because it contains important information for you.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

#### What is in this leaflet

1. What Fucicort Lipid cream is and what it is used for
2. What you need to know before you use Fucicort Lipid cream
3. How to use Fucicort Lipid cream
4. Possible side effects
5. How to store Fucicort Lipid cream
6. Contents of the pack and other information

#### 1. What Fucicort Lipid cream is and what it is used for

Fucicort Lipid cream contains two different types of medicine. One medicine is an antibiotic (fusidic acid) and the other medicine is a corticosteroid (betamethasone valerate). Fusidic acid works by halting the growth of bacteria and betamethasone works by reducing any inflammation and itchiness of your skin. Fucicort Lipid cream is used in the treatment of skin disorders where infections are caused by bacteria which are sensitive to fusidic acid.

Always use this medicine exactly as your doctor has told you.

You must talk to a doctor if you do not feel better or if you feel worse after using the treatment.

#### 2. What you need to know before you use Fucicort Lipid cream

##### Do not use Fucicort Lipid cream:

- if you are allergic to fusidic acid, bethametasone or any of the other ingredients of this medicine (listed in section 6).
- for children below one year of age and under nappies.

##### Do not use Fucicort Lipid cream to treat:

- systemic fungal infections (deep infections caused by a fungus)
- skin conditions caused by a fungus, bacteria or virus
- rosacea (severe redness, especially in the centre of your face)
- eczema around the mouth
- tuberculosis (TB)
- acne



### **Warnings and precautions**

Talk to your doctor or pharmacist before using Fucicort Lipid cream.

Do not use Fucicort Lipid cream for longer than necessary, and no longer than your doctor has instructed. You should not use Fucicort Lipid cream for more than two weeks.

Avoid getting Fucicort Lipid cream into your eyes, in open wounds or on mucous membranes (delicate skin lining, eg in the mouth or nostrils).

Contact your doctor if you experience blurred vision or other visual disturbances.

Fucicort Lipid cream may mask possible symptoms of infection.

Fucicort Lipid cream may potentially increase your risk of infectious diseases, worsen existing infections or reactivate dormant infections.

### **Children and adolescents**

Fucicort Lipid cream should be used with caution in children. Avoid large amounts, covering your skin with dressings or bandages (occlusion) and prolonged treatment.

### **Other medicines and Fucicort Lipid cream**

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.

You can use Fucicort Lipid cream together with other medicines.

### **Pregnancy and breast-feeding**

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before using this medicine.

**Pregnancy:** You should only use Fucicort Lipid cream as instructed by your doctor.

**Breast-feeding:** You can use Fucicort Lipid cream for a short period of time if you are breast-feeding. Ask your doctor for advice. You must not use Fucicort Lipid cream on your breasts if you are breast-feeding.

### **Driving and using machines**

Fucicort Lipid cream does not affect your ability to drive or use machines.

### **Fucicort Lipid cream contains methylparahydroxybenzoate (E218), propylparahydroxybenzoate (E216) (preservatives), cetostearyl alcohol and potassium sorbate.**

The content of methylparahydroxybenzoate (E218) and propylparahydroxybenzoate (E216) may lead to allergic reactions (possibly delayed). Cetostearyl alcohol and potassium sorbate may lead to local skin reactions. This may happen at any time after you use your medicine. Please read section 4 so you can spot any signs this may be happening to you.

## **3. How to use Fucicort Lipid cream**

Always use this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

### **Dosing**

Adults and children: Apply a thin layer 2-3 times a day for up to 2 weeks.

### **Instructions for use**

Only use Fucicort Lipid cream on inflamed skin.



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Wash your hands every time you have applied Fucicort Lipid cream unless you are treating the skin on your hands.

**If you use more Fucicort Lipid cream than you should**

Contact your doctor or pharmacist if you have used more Fucicort Lipid cream than described in this leaflet or more than your doctor has prescribed or if you feel unwell.

**If you forget to use Fucicort Lipid cream**

If you forget to apply Fucicort Lipid cream you should apply it as soon as you remember and then continue to use Fucicort Lipid cream as before.

**4. Possible side effects**

Like all medicines, this medicine can cause side effects, although not everybody gets them.

**Uncommon side effects, can affect up to 1 in 100 people:**

- Allergic reaction
- Redness or rash
- Burning feeling in the skin
- Itching
- Dry skin
- Application site pain
- Application site irritation

**Rare side effects, can affect up to 1 in 1000 people**

- Skin redness
- Hives
- Rash
- Application site swelling
- Application site blisters

**Frequency not known (cannot be estimated from the available data)**

- Blurred vision

**Side effects caused by treatment with corticosteroids, such as betamethasone are:**

- Thinning of your skin
- Eczema
- Eczema around your mouth
- Stretch marks
- Small veins near the surface of your skin become visible
- Persistent reddening of your skin
- Reddening of your skin
- Lightening of your skin colour
- Increased growth of your body hair
- Excessive sweating
- Bleeding in your skin can arise with prolonged use

**Systemic side effects caused by treatment with strong corticosteroids, such as betamethasone are:**

- Adrenal glands may stop working properly, especially with prolonged use
- Complications if used too close to the eyes (e.g. increased pressure in the eyes and glaucoma)



## Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via [the national reporting system](#) listed in [Appendix V](#). By reporting side effects you can help provide more information on the safety of this medicine.

## 5. How to store Fucicort Lipid cream

Do not store above 30° C.

Do not keep the tube for more than 3 months after you first open it.

Do not use this medicine after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of that month.

Keep this medicine out of the sight and reach of children.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

## 6. Contents of the pack and other information

### What Fucicort Lipid cream contains

- The active substances are: Fusidic acid 20 mg/g and betamethasone (as valerate) 1 mg/g.
- The other ingredients are: steareth-21, white soft paraffin, cetostearyl alcohol, liquid paraffin, hypromellose, citric acid monohydrate, potassium sorbate, purified water and preservatives: methylparahydroxybenzoate (E218), propylparahydroxybenzoate (E216), all-rac- $\alpha$ -tocopherol.

### What Fucicort Lipid cream looks like and contents of the pack

Fucicort Lipid cream is a white cream and comes in tubes of 5g, 15 g, 30 g and 60 g.

Not all pack sizes may be marketed.

### Marketing Authorisation Holder and Manufacturer

#### Marketing Authorisation Holder:

LEO Pharma A/S  
Industriparken 55  
DK-2750 Ballerup

#### Manufacturer:

LEO Laboratories Ltd.  
285 Cashel Road, Crumlin  
Dublin 12  
Ireland

### This medicinal product is authorised in the Member States of the EEA under the following names:

Austria: Fucibet Lipid 20 mg/g + 1mg/g Creme

Bulgaria: Fucibet Lipid 20 mg/g + 1mg/g cream

Czech Republic: FUCICORT LIPID 20 MG/G + 1 MG/G



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Denmark: Fusidinsyre/betamethasonvalerat "Leo"

Italy: FUCIMIXBETA® 20 mg/g + 1 mg/g crema

Norway: Fusidinsyre/Betametason LEO

Poland: Fucibel® Lipid

Slovakia: Fucicort Lipid 20 mg/g + 1 mg/g krém

Sweden: Fusidinsyra/Betametason LEO

**This leaflet was last revised in <{MM/YYYY}> <{month YYYY}>.**



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