

## Package leaflet: Information for the user

### FUCIDINE 2 PERCENT, cream

Fusidic acid

**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 symptoms are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This also applies to any possible side effects not listed in this leaflet. See section 4.

#### What is in this leaflet

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

#### 1. What FUCIDINE 2 PERCENT, cream is and what it is used for

Pharmacotherapeutic class: ATC code: D06AX01.

This medicine, which active substance is fusidic acid, is an antibiotic.

This medicine is recommended for the treatment of skin infections caused by bacteria belonging to the group of staphylococci or streptococci.

#### 2. What you need to know before you use FUCIDINE 2 PERCENT, cream

##### Do not use FUCIDINE 2 PERCENT, cream:

- if you are allergic to fusidic acid or any of the other ingredients of this medicine, listed in Section 6.

##### Warnings and precautions

Talk to your doctor or pharmacist before using FUCIDINE 2 PERCENT, cream.

This medicinal product contains cetyl alcohol and potassium sorbate, which may cause local skin reactions (e.g. eczema).

This medicine contains butylhydroxyanisole (E320), which may cause local skin reactions (e.g. eczema) or irritation to the eyes and mucous membranes.

Fucidine should be used with care when applied in the proximity of the eyes.

##### Children and adolescents

Not applicable.

##### Other medicines and FUCIDINE 2 PERCENT, cream

Tell your doctor or pharmacist if you are taking, have recently taken or are likely to take any other medicines.

##### FUCIDINE 2 PERCENT, cream with food and drink

Not applicable.

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

This medicine can be used during pregnancy and breast-feeding.

If you are breast-feeding, do not apply Fucidine on the breast.

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.

### **Driving and using machines**

Fucidine has no effect or negligible influence on the ability to drive and use machines.

**FUCIDINE 2 PERCENT, cream contains butylhydroxyanisole (E320), cetyl alcohol and potassium sorbate.**

### **3. How to use FUCIDINE 2 PERCENT, cream**

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

#### **Posology**

Local applications, with or without a dressing, once or twice a day after cleaning the infected area.

Avoid applying in a thick layer.

#### **Duration of treatment**

It is recommended to limit treatment to one week.

#### **If you use more FUCIDINE 2 PERCENT, cream than you should**

Overdose is unlikely to occur.

If you use more Fucidine than you should, contact your doctor or pharmacist.

#### **If you forget to use FUCIDINE 2 PERCENT, cream**

Do not take a double dose to make up a forgotten dose.

#### **If you stop using FUCIDINE 2 PERCENT, cream**

Not applicable.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist for more information.

### **4. Possible side effects**

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

#### **Uncommon side effects: may affect up to 1 in 100 people:**

- local skin reactions (including contact dermatitis, eczema)
- cutaneous eruption (rash)
- itching (pruritus), redness of the skin (erythema)
- pain at site of application (including skin burning sensation), irritation at site of application

#### **Rare side effects (may affect up to 1 in 1,000 people):**

- allergic reaction
- conjunctivitis
- swelling of the neck and face
- urticaria
- blisters

## Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system: Agence nationale de sécurité du médicament et des produits de santé (French National Agency for the Safety of Medicines and Health Products - ANSM) and the network of Regional Pharmacovigilance Centres – Website: [www.ansm.sante.fr](http://www.ansm.sante.fr)

By reporting side effects, you can help provide more information on the safety of this medicine.

## 5. How to store FUCIDINE 2 PERCENT, CREAM

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

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.

Store at a temperature not exceeding 25 °C.

Do not throw away any medicines via waste water 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 FUCIDINE 2 PERCENT, cream contains

- The active substance is:  
Fusidic acid.....2,000 g

For 100 g of cream.

- The other ingredients are:  
Butylhydroxyanisole (E320), cetyl alcohol, glycerol, liquid paraffin (containing all-rac-alpha-tocopherol), potassium sorbate, polysorbate 60, vaseline (containing all-rac-alpha-tocopherol), hydrochloric acid (for pH adjustment), purified water.

### What FUCIDINE 2 PERCENT, cream looks like and contents of the pack

This medicine is formulated as a cream. Box containing 1 tube of 15 g or 30 g.

Not all pack sizes may be marketed.

### Marketing Authorisation holder

**LABORATOIRES LEO**  
2 RUE RENE CAUDRON  
78960 VOISINS LE BRETONNEUX  
FRANCE

### Exploitant

**LABORATOIRES LEO**  
PARC D'AFFAIRES LE VAL SAINT QUENTIN  
2 RUE RENE CAUDRON  
78960 VOISINS LE BRETONNEUX  
FRANCE

### Manufacturer

**LEO LABORATORIES LTD**  
285 CASHEL ROAD  
DUBLIN 12  
IRELAND

## **Names of the medicine in the Member States of the European Economic Area**

Not applicable.

**This leaflet was last revised in:**

[to be completed by the holder]

### **Other sources of information**

#### **HEALTH ADVICE/EDUCATION**

#### **IMPORTANT INFORMATION ABOUT ANTIBIOTICS**

Antibiotics are effective against infections caused by bacteria. They have no effect against infections caused by viruses.

Your doctor has chosen to prescribe this antibiotic for you because it is precisely right for you and your current illness.

Bacteria can survive or multiply despite the antibiotic. This phenomenon is called resistance, and it renders some antibiotics inactive.

Resistance increases when antibiotics are misused or used inappropriately.

You may facilitate the appearance of resistant bacteria and thus delay your recovery, or even make the medicine ineffective, if you do not comply with:

- the prescribed dose,
- the administration times,
- the treatment duration.

**Consequently, in order to ensure that this medicine remains effective:**

**1- Use antibiotics only when prescribed by your doctor.**

**2- Strictly follow your prescription.**

**3- Do not re-use an antibiotic without a medical prescription even if you think you have an apparently similar illness.**

**4- Never give your antibiotic to another person because maybe it is not be adapted to his/her illness.**

**5- After completion of your treatment, return all unfinished boxes to your pharmacist to ensure a correct and appropriate drug disposal.**

Detailed information on this medicine is available on the ANSM website (France).