

Package leaflet: Information for the user

Fucidin 30 mg/100 cm² impregnated dressing sodium fusidate

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

1. What Fucidin is and what it is used for

The active substance of Fucidin is sodium fusidate which is an antibiotic. Fucidin is used for skin infections caused by bacteria sensitive to sodium fusidate in children from 1 year of age and adults.

2. What you need to know before you use Fucidin

Do not use Fucidin:

- if you are allergic to sodium fusidate or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor or pharmacist before using Fucidin.

If you use this product regularly or during a long period, there is a risk that the bacteria against which this product is active become resistant to sodium fusidate. Therefore, it is possible that this product does not work properly for you after prolonged use.

When Fucidin is used on the face, care should be taken to avoid contact with the eyes as the excipients in the impregnated dressing may cause eye irritation.

Fucidin must not be used on severely injured skin.

Talk to you doctor or pharmacist before using Fucidin if you are taking statins (medicines to lower blood cholesterol).

Other medicines and Fucidin

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

There are no known interactions with other medicinal products. However you must tell your doctor or pharmacist if you are taking medicines to lower blood cholesterol, such as statins. Taking Fucidin orally (e.g. tablets) and statins at the same time may lead to a condition called rhabdomyolysis, with symptoms of muscle weakness, tenderness or pain. There is no evidence of topical Fucidin and statins causing rhabdomyolysis, but tell your doctor immediately if you take statins and Fucidin at the same time and experience muscle weakness, tenderness or pain.

Pregnancy, breast-feeding and fertility

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 taking this medicine.

Pregnancy

Fucidin can be used during pregnancy.

Breast-feeding

Fucidin can be used during breast-feeding, but it is recommend to avoid applying Fucidin on the breast.

Fertility

There are no known effects on fertility.

Driving and using machines

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

Fucidin contains cetyl alcohol, wool fat and butylhydroxytoluene (E321)

Fucidin contains cetyl alcohol and wool fat. These excipients may cause local skin reactions (e.g. contact dermatitis). Fucidin contains butylhydroxytoluene (E321) which may cause local skin reactions (e.g. contact dermatitis) or irritation to the eyes and mucous membranes.

3. How to use Fucidin

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

Use in adults and children: apply Fucidin once a day.

Fucidin is for cutaneous use only.

Instructions for use

- Before applying Fucidin, wash and dry your hands.
- Remove the two pieces of parchment paper around the impregnated dressing .
- Apply the impregnated dressing to the infected area of the skin and keep it in place with for example a bandage. The impregnated dressing must cover the entire infected area.
- Change the impregnated dressing once daily.

If needed, you can cut the impregnated dressing into a suitable size before removing the parchment paper.

If you use more Fucidin than you should

Overdose of Fucidin is unlikely to occur.

If you forget to use Fucidin

If you forget to apply Fucidin, you should apply it as soon as you remember and then continue to use Fucidin as before.

If you stop using Fucidin

Use the whole treatment course you have been prescribed. If you stop the treatment prematurely, the skin infection can return or might not heal.

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

4. Possible side effects

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

The most frequently reported adverse reactions during treatment are various skin reactions such as pruritus and rash, followed by various application site conditions such as pain and irritation, which all occurred in less than 1 % of patients.

Uncommon side effects: (may affect up to 1 in 100 people)

- eczema and irritation of the skin (incl. dermatitis and contact dermatitis)
- rash (incl. generalised, erythematous, pustular, vesicular, maculopapular and papular rash)
- itching (pruritus)
- redness of the skin (erythema)
- application site pain (incl. skin burning sensation)
- application site irritation

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

- hypersensitivity
- inflammation of the eyes (conjunctivitis)
- rash, hives and swelling (angioedema)
- hives (urticaria)
- blisters

Additional side effects in children

Frequency, type and severity of adverse reactions in children are expected to be the same as in adults.

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 listed in Appendix V. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Fucidin

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

Do not store above 30°C.

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

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 Fucidin contains

- The active substance is sodium fusidate. One impregnated dressing (10 cm x 10 cm) contains 30 mg/100 cm² sodium fusidate
- The other ingredients are cetyl alcohol, wool fat, liquid paraffin, white soft paraffin, all-*rac*- α -tocopherol, butylhydroxytoluene (E321)

What Fucidin looks like and contents of the pack

Fucidin is an impregnated dressing. The impregnated dressing consists of a 10 cm x 10 cm piece of cotton gauze impregnated with ointment. The ointment is off-white to white in colour. The impregnated dressing is placed between two pieces of parchment paper and sealed in an aluminium foil sachet.

Pack sizes

10 impregnated dressings (10 cm x 10 cm)

50 impregnated dressings (10 cm x 10 cm)

Not all pack sizes may be marketed.

Marketing Authorisation Holder

LEO Pharma A/S
Industriparken 55
2750 Ballerup
Denmark

Manufacturer

LEO Laboratories Ltd
285 Cashel Road
Dublin 12
Ireland

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

Czech Republic:	FUCIDIN impregnovaný obváz
Denmark:	Natriumfusidat LEO
Ireland:	Fucidin® 30mg/100cm ² impregnated dressing
Italy:	Fucymed
Slovakia:	Fucidin 30 mg/100 cm ² impregnovaný obváz

This leaflet was last revised in {MM/YYYY}.