

This medicine can be sold with a physician's prescription only.

Fucidin® Ointment

Fucidin® Cream

Active ingredient:

Fucidin Ointment contains Sodium fusidate 2%

Fucidin Cream contains Fusidic acid 2%

For a list of inactive ingredients, see section 6 "Additional information" and section "Important information about some of the ingredients of the medicine".

Read this entire leaflet carefully before using this medicine.

This leaflet contains concise information about the medicine. If you have any further questions, refer to the physician or pharmacist.

This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is the same as yours.

1. What is the medicine intended for?

Antibiotic for treatment of bacterial skin infections susceptible to the preparation.

Therapeutic group: Topical antibiotic.

2. Before using the medicine

Do not use the medicine if:

- You are hypersensitive (allergic) to the active ingredient or to any other of the additional ingredients contained in the medicine (see section 6).

Special warnings regarding the use of the medicine:

If you are sensitive to any kind of food or medicine, inform your physician before using this medicine.

- Do not use Fucidin Ointment/Cream for a long time as the germs (bacteria) may no longer be killed by the antibiotic. Thus, reduce the effectiveness of the medicine.
- Avoid getting the ointment in your eyes (e.g., accidentally from your hands or by using it too close to your eyes) as it could irritate (sting) them.

If you are taking, or have recently taken, other medicines including non prescription medicines and nutritional supplements, tell the physician or pharmacist.

Pregnancy and breast-feeding

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

- Fucidin Ointment/Cream may be used if you are pregnant or think you might be pregnant.
- Fucidin Ointment/Cream may be used if you are breast-feeding, but do not apply the medicine to the breast.

Driving and using machines

This medicine should not have any effect on your ability to drive or use machinery. Nevertheless, if you feel any side effect that may harm your ability to drive or use machinery, consult your physician.

Important information about some of the ingredients of the medicine:

Fucidin Cream contains:

- Cetyl alcohol and potassium sorbate which may give you an itchy red rash with heat and swelling on your skin where the cream is used (e.g. contact dermatitis).
- Butylhydroxytoluene which may give you an itchy red rash with heat and swelling on your skin where the cream is used (e.g.

contact dermatitis) and irritation to the eyes and mucous membranes (e.g. mouth, nose and ears).

Fucidin Ointment contains:

- Cetyl alcohol and Wool fat which may give you an itchy red rash with heat and swelling on your skin where the cream is used (e.g. contact dermatitis).
- Butylhydroxytoluene which may give you an itchy red rash with heat and swelling on your skin where the cream is used (e.g. contact dermatitis) and irritation to the eyes and mucous membranes (e.g. mouth, nose and ears).

3. How to use the medicine

Always use according to your physician's instructions. Check with your physician or pharmacist if you are not sure.

The dosage and method of administration will be determined by the physician only. The usual treatment time is up to two weeks, consult your physician before using this medicine for a longer period of time. Prolong use may cause resistance to the medicine.

The usual recommended dose is: apply the cream/ointment on the affected area 3-4 times a day, but less often if the area is covered with a bandage.

You should notice an improvement after a few days of using Fucidin Cream/Ointment. If there is no improvement after seven days, stop using the medicine and refer to the physician. If you forget to apply this medicine at the scheduled time, use it as soon as you remember. Afterwards, carry on use at the usual scheduled time.

Directions of use: Do not swallow. This medicine is intended for external use only.

Wash your hands before using Fucidin Ointment/Cream. Rub the Ointment/Cream on the skin. If your physician has told you to use Fucidin Ointment/Cream on your face, avoid contact with your eyes. If the preparation accidentally came in contact with the eyes, rinse them immediately with cold water and then with eyewash solution if possible. Your eye may sting.

Wash your hands after using Fucidin Ointment/Cream (unless you are using the preparation to treat your hands).

If a child has accidentally swallowed this medicine, proceed immediately to a physician or a hospital emergency room and bring the medicine package with you.

Complete the full course of treatment as recommended by the physician.

Even if there is an improvement in your health, do not stop treatment with this medicine without consulting your physician.

Medicines should not be taken in the dark! Check the label and dose each time you use the medicine. Wear glasses if you need them.

If you have any further questions regarding the use of this medicine, consult a doctor or pharmacist.

4. Side effects

Like all medicines, the use of Fucidin Ointment/Cream may cause side effects in some of the users. Do not be alarmed while reading the list of side effects. You may not suffer from any of them.

Refer to a physician immediately if you suffer from any of the following side effect: allergic reaction. This is rare (appears in 1 user out of 1,000), difficulty breathing, tingling or swelling of the lips and mouth, swelling of the face or throat, severe skin rash.

Additional side effects:

If additional less serious side effects occur, refer to your physician as soon as possible. Uncommon side effects - effects which appear in 1-10 users out of 1,000:

- Rash or itch
- Redness of the skin
- Contact dermatitis or eczema (itchy red rash with heat and swelling in the area where the ointment/cream is used).
- Pain, irritation (stinging) or burning in the area where the medicine is used.

Rare side effects, effects which appear in 1-10 users out of 10,000:

- Itchy and watery discharge from the eyes.
- Swelling of the face, lips, throat or tongue which may cause difficulty in swallowing or breathing.
- Hives or blisters.

These side effects may also occur in children who use the medicine.

If a side effect appears, if one of the side effects worsens, or if you suffer from a side effect not listed in this leaflet, consult your physician.

Side effects can be reported to the Ministry of Health by clicking on the link www.health.gov.il "דיווח על תופעות לוואי" that can be found on the home page of the Ministry of Health website (www.health.gov.il) directing to the online form of adverse events reporting or via the following link:

<https://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffectMedic@moh.gov.il>

5. How to store the medicine?

- Avoid poisoning! This medicine, and all other medicines, must be stored in a closed place out of the reach of children and/or infants, to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by a physician!
- Do not use the medicine after the expiry date (exp. date) stated on the package. The expiry date refers to the last day of that month.
- Do not store above the temperature of 30°C.
- After opening the tube, do not use Fucidin Ointment more than three months and Fucidin Cream more than a month.

6. Additional information

In addition to the active ingredient, this medicine also contains:

Fucidin Ointment:

White soft paraffin, liquid paraffin, Wool fat, Cetyl alcohol, butylhydroxytoluene, all-rac- α -tocopherol.

Fucidin Cream:

Cetyl alcohol, glycerol (85%), liquid paraffin, polysorbate 60, white soft paraffin, potassium sorbate, butylhydroxyanisole, hydrochloric acid, purified water, all-rac- α -tocopherol.

What the medicine looks like and content of the package:

Fucidin Ointment: yellowish to white ointment.

Fucidin Cream: white cream

Approved package sizes: 5, 15, 30 gram. Not all package sizes may be marketed.

This leaflet was checked and approved by the MoH in March, 2016.

Drug registration number at the national medicines registry of the Ministry of Health:

Fucidin Ointment 056282652800

Fucidin Cream 056292652100

Manufacturer and address:

Leo Laboratories Ltd., Dublin, Ireland.

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