

Patient package insert according to Pharmacists' Regulations (Preparations) –1986

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

Fucicort® Cream

Composition: **Fucicort Cream** contains Fusidic acid 2% and Betamethasone (as valerate) 0.1%.

Inactive ingredients and allergens - see section 6 “Additional information” and section 2 “Important information about some of the ingredients of the medicine”.

Read this entire leaflet carefully before you start using the medicine. This leaflet contains concise information about the medicine. If you have any further questions, refer to the doctor or to the pharmacist.

This medicine has been prescribed for your treatment. Do not pass it on to others. It may harm them, even if you think that their medical condition is similar.

1. **What is the medicine intended for?**

For treating skin infections of various types, such as eczema, which have secondary bacterial infection.

Medical Activity:

Fucicort Cream contains two different active ingredients: Fusidic acid which is a type of antibiotic and Betamethasone valerate, which is a type of corticosteroid (steroid). These two active ingredients work at the same time in different ways.

Fucicort Cream works by:

- The antibiotic killing germs (bacteria) that cause infections.
- The corticosteroid reducing any swelling, redness or itchiness of your skin.

Therapeutic group: Combination of corticosteroids (steroid) with antibiotics.

2. **Before using the medicine**

Do not use the medicine:

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| <ul style="list-style-type: none">If you are sensitive (allergic) to the active ingredients (Fusidic acid or Betamethasone valerate) or any of the other ingredients in this medicine (see Section 6) To treat a skin condition caused by a fungus (such as athlete’s foot). To treat a skin condition caused by a virus (such as cold sores (herpes) or chickenpox). To treat skin conditions caused by bacteria only (such as boils or spots). To treat skin conditions caused by tuberculosis or syphilis. To treat a skin condition called perioral dermatitis. This is a red spotty rash around the mouth or the chin. To treat a skin condition called rosacea. This is redness and inflammation over the nose and the cheeks. Ask your doctor if you are unsure. |
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Special warnings regarding the use of the medicine:

Before and during treatment with Fucicort Cream, consult a doctor or a pharmacist:

- Do not use the cream on yourself or a child for more than two weeks; this in order to prevent development of bacteria resistant to antibiotics and avoid the side effects that may be caused to you by the steroid.
- Take special care if you are going to use **Fucicort Cream** near your eyes or the eyes of a child. If the cream gets into the eye, this may lead to glaucoma.
- Contact the doctor if you experience blurred vision or other visual disturbances.
- If you use the cream over a long time or in large amounts it may make the chance of getting any side effects or infections higher. Also, your skin may get more sensitive to this medicine.
- You must not use the medicine on your face for a long period of time.
- You must not use **Fucicort Cream** on open wounds or sensitive areas such as the nostrils, ears, lips or genitals, unless your doctor has told you to.
- You must not use **Fucicort Cream** on thin skin, skin ulcers, broken veins or acne, unless your doctor has told you to.
- Adrenal suppression may occur. Signs are tiredness, depression and anxiety. This can be reversed by stopping **Fucicort Cream**.

Do not smoke or go near naked flames - risk of severe burns. Fabric (clothing, bedding, dressings etc.) that has been in contact with this product burns more easily and is a serious fire hazard. Washing clothing and bedding may reduce product build-up but not totally remove it.

If there is a worsening of your condition during use, consult your doctor – you may be experiencing an allergic reaction, have an infection or your condition requires a different treatment.

If you experience a recurrence of your condition shortly after stopping treatment, within 2 weeks, do not use the cream again without consulting your doctor, unless your doctor has previously advised you to so.

If your condition has resolved and on recurrence the redness extends beyond the initial treatment area and you experience a burning sensation, refer to the doctor before restarting treatment.

Drug interactions

If you are taking or have recently taken or if you might take any other medicines, including non-prescription drugs and nutrition supplements, tell the doctor or pharmacist.

Pregnancy, breast-feeding and fertility

If you are pregnant or breastfeeding, think you might be pregnant or planning to become pregnant, ask your doctor or pharmacist for advice before using this medicine.

- If you are pregnant or think you might be pregnant: Do not use **Fucicort Cream** during pregnancy, unless you are told to do so by your doctor.
- If you are breast-feeding: **Fucicort Cream** may be used by women who are breast-feeding, but the cream should not be applied to the breasts to avoid accidental ingestion by the infant.

Tell the doctor if you become pregnant while using this medicine.

Driving and using machines

This medicine should not have any effect on your ability to drive or use machines. Check with your doctor if you feel any side effect that may stop you from driving or using machines.

Important information about some of the ingredients of the medicine

- This medicine contains Cetostearyl alcohol. This ingredient may give you an itchy rash and inflammation on your skin where your medicine is used.
- This medicine contains Chlorocresol. This is a preservative. It may cause you an allergic reaction. Please read Section 4 so you can spot any signs that this may be happening to you.

Please ask your doctor if you are worried about any of the ingredients in this medicine.

3. **How to use this medicine**

Always use the medicine according to the doctor’s instructions. Check with the doctor or pharmacist if you are not sure about the dosage and treatment regimen of the medicine.

How to use Fucicort Cream

This medicine is only for use on your skin or the skin of a child. Do not swallow it. The medicine is intended for external use only.

Remove the cap. Check that the seal is not broken before you first use the cream. Then push the spike in the cap through the seal on the tube.

Always wash your hands before using **Fucicort Cream**. Rub the cream gently on the skin. If you use it on your face, or the face of a child be careful to avoid your eyes or the eyes of a child.

Unless you are using the cream to treat your hands, always wash your hands after using **Fucicort Cream**.

If you accidentally get any medicine in your eyes, or in a child’s eyes, wash it out with cold water immediately. Then rinse the eyes with an eye wash solution if possible. Your eye may sting. If you start to have any problems with your sight or your eye is sore, contact your doctor immediately.

Dosage and duration of treatment

The dosage and treatment will be determined by the doctor only. **Do not exceed the recommended dose.**

The usual treatment time is up to two weeks. Consult your doctor before using this medicine for longer period of time.

You should notice your skin improve after just a few days of using the cream. If there is no improvement after 7 days, you should stop using the cream and refer to your doctor.

Usually you should use this medicine twice each day. Use it in the morning and evening. To remind you to use the medicine, it may help to use it when you do another regular action, such as brushing your teeth.

If you have been told to cover the skin with any bandages you may not need to use the medicine so often.

A nappy on a baby may act as a dressing. Follow your doctor’s instructions.

If you use more Fucicort Cream than you should

If you have used more **Fucicort Cream** than you should, refer to a doctor immediately and bring the package of the medicine with you. You may need to stop using this medicine.

If a child has accidentally swallowed the medicine, refer immediately to a doctor or to a hospital emergency room and bring the package of the medicine with you.

If you forget to use the medicine

If you forget to use the cream at the right time, use it as soon as you remember. Then use this medicine again at the usual time.

Do not use a double dose to make up for a forgotten dose.

Continue with the treatment as recommended by the doctor.

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

Do not take medicines in the dark! Check the label and the dose each time you take a medicine. Wear glasses if you need them.

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

4. **Side effects**

Like any medicine, the use of **Fucicort Cream** may cause side effects in some users. Do not be alarmed while reading the list of side effects. You may not suffer from any of them.

Important side effects to pay attention to:

Contact your doctor immediately if any of the following happens; you may need to stop treatment:

- You have difficulty breathing**
- Your face or throat swells**
- Your skin develops a serious rash**

The following less serious side effects have also been reported. If any of them last a long time or cause problems, contact your doctor as soon as possible:

Any of the side effects listed below are more likely to appear if the medicine is used for a long time, in large amounts or on skin folds (such as armpits or under breasts). These side effects are more likely in babies and children.

These side effects are also more likely if the skin is covered with a bandage or nappy.

Uncommon side effects (side effects that appear in 1-10 users out of 1,000):

- Itchy rash and skin inflammation in the area where the medicine is used
- Worsening of your eczema
- Burning feeling
- Itching

- Dry skin
- Application site pain
- Application site irritation **Rare side effects** (side effects that appear in 1-10 users out of 10,000)
- Skin redness
- Hives
- Skin rash
- Application site swelling
- Application site blisters

Side effects of unknown frequency (side effects whose frequency has not yet been determined):

- Blurred vision

Some side effects are known to be caused by betamethasone valerate (steroid), one of the ingredients in **Fucicort Cream**. Tell your doctor if one or more of the following side effects occur:

- Adrenal glands may stop working properly. Signs are tiredness, depression and anxiety.
- Glaucoma
- Thinning of the skin
- Red spotty rash around the mouth or chin
- Stretch marks
- Small veins near the surface of the skin become visible
- Changes in growth of your body hair
- Excessive sweating
- Lightening of your skin colour
- Redness and pimples around the mouth
- Redness of the skin, nose or mouth
- Formation of cataracts
- Steroid withdrawal reaction:

If used continuously for prolonged periods, a withdrawal reaction may occur on stopping treatment with some or all of the following effects: redness of the skin which can extend beyond the initial area treated, a burning or stinging sensation, intense itching, peeling of the skin, oozing open sores.

If a side effect appears, if one of the side effects worsens or when you suffer from a side effect not mentioned in this leaflet, consult the doctor

Side effects can be reported to the Ministry of Health by clicking on the link "דיווח על תופעות לוואי עקב טיפול תרופתי" 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://sideeffects.health.gov.il>

5. **How to store the medicine**

- Avoid poisoning! This medicine, and any other medicine, must be stored in a safe place out of the reach and sight of children and/or infants, to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.
- Do not use the medicine after the expiry date (EXP) stated on the package. The expiry date refers to the last day of that month.
- Storage conditions:** store below 30°C.
- Do not use this medicine for more than three months after first opening.
- Medicines should not be disposed of via wastewater or household waste. Ask the pharmacist how to dispose of medicines no longer in use. These measures will help to protect the environment.

6. **Additional information**

In addition to the active ingredients, the medicine also contains:

White soft paraffin, cetostearyl alcohol, liquid paraffin, macrogol cetostearyl ether, sodium dihydrogen phosphate dihydrate, chlorocresol, sodium hydroxide, purified water, all-rac-α-tocopherol.

What the medicine looks like and what the package contains: A tube containing 15 grams white coloured cream.

Manufacturer and his address: LEO Laboratories Ltd., Dublin, Ireland

Revised in August 2022 according to MOH guidelines.

Drug registration number at the national medicines registry of the Ministry of Health: 056-30-26527-00

Registration holder: Dexcel® Ltd.

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