

# PACKAGE LEAFLET: INFORMATION FOR THE USER

## Fucidin<sup>®</sup> H cream

### Fusidic acid and hydrocortisone acetate

**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, pharmacist or nurse.
- This medicine has been prescribed for you. 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

#### **What is in this leaflet:**

1. What Fucidin<sup>®</sup> H cream is and what it is used for
2. Before you use Fucidin<sup>®</sup> H cream
3. How to use Fucidin<sup>®</sup> H cream
4. Possible side effects
5. How to store Fucidin<sup>®</sup> H cream
6. Contents of the pack and other information

#### **1. What Fucidin<sup>®</sup> H cream is and what it is used for**

Fucidin H cream contains 2 different types of medicine. One medicine is called fusidic acid. It is a type of antibiotic. The other medicine is called hydrocortisone acetate. It is a type of corticosteroid (steroid). These 2 medicines work at the same time in different ways.

Fucidin H cream works by:

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

Fucidin H cream is used to treat:

- Conditions where the skin is inflamed (eczema or dermatitis) and also infected by germs (bacteria).

Corticosteroid creams, ointments and other topical preparations come in four different potencies or strengths. These are known as mild, moderately potent, potent or very potent. Healthcare professionals will usually refer to topical corticosteroid potency rather than strength. A potent or strong corticosteroid has a much stronger effect than a mild corticosteroid when using the same amount. The percentage of active ingredient that is sometimes included on product packaging does not indicate potency. Hydrocortisone is classed as a mild corticosteroid.

Your healthcare professional will prescribe or advise a steroid of the appropriate potency for your condition.

#### **2. What you need to know before you use Fucidin<sup>®</sup> H cream**

### **Do not use Fucidin H cream**

- If you are allergic (hypersensitive) to fusidic acid or hydrocortisone acetate.
- If you are allergic (hypersensitive) to any of the other ingredients in your medicine. You can find a list of these ingredients in section 6 of this leaflet.
- To treat a skin condition called acne rosacea. This is redness and inflammation over your nose and cheeks. Ask your doctor if you are unsure.
- To treat a skin condition called perioral dermatitis. This is a red spotty rash around your mouth or chin.
- To treat skin conditions caused by tuberculosis or syphilis.
- To treat skin conditions caused only by bacteria, such as boils or spots.
- To treat a skin condition caused by a virus, such as cold sores or chickenpox.
- To treat a skin condition caused by a fungus, such as athlete's foot.

### **Warnings and precautions**

#### **Talk to your doctor, pharmacist or nurse before using Fucidin H cream**

- Take special care if you are going to use this medicine near your eyes or the eyes of a child. If the cream gets into the eye, this may lead to glaucoma.
- Contact your 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 higher. Also your skin may get more sensitive to this medicine.
- You must not use the medicine for a long time on your face.
- Unless your doctor has told you to, you must not use Fucidin H 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 Fucidin H cream on thin skin, skin ulcers, broken veins or acne.
- Adrenal suppression may occur. Signs are tiredness, depression and anxiety. This can be reversed by stopping Fucidin H cream.
- Treatment should be stopped after 7 days if your skin has not improved after using Fucidin H 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 prescriber – 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 restart using the cream without consulting your prescriber unless your prescriber 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, please seek medical advice before restarting treatment.

### **Other medicines and Fucidin H cream**

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

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

Please ask your doctor or pharmacist for advice before using Fucidin H cream:

- If you are pregnant, or think you are pregnant.

You must not use your medicine for a long time or in large amounts. You must ask your doctor for advice.

- If you are breast-feeding.

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

### **Driving and using machines**

Usually your medicine will have very little 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 Fucidin H cream**

Fucidin H cream contains:

- Butylhydroxyanisole (E320). This may give you an itchy rash and inflammation on your skin where your medicine is used. This may also cause irritation to the eyes and mucous membranes (such as lips or genital area).
- Cetyl alcohol. This may give you an itchy rash and inflammation on your skin where your medicine is used.
- Potassium sorbate. This may give you an itchy rash and inflammation on your skin where your medicine is used.

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

### **3. How to use Fucidin<sup>®</sup> H cream**

Always use Fucidin H cream exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

#### **How to put on Fucidin H cream**

This medicine is only for using on your skin or the skin of a child. Do not swallow it. Do not put it inside your body.

Remove the cap. Check 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 Fucidin H cream. Rub the medicine gently on the skin. If you use it on your face be careful to avoid your eyes.

Unless you are using the cream to treat your hands, always wash your hands after using Fucidin H cream.

If you accidentally get any medicine in your eye, wash it out with cold water straight away. Then bathe your eye with eyewash 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.

#### **How much Fucidin H cream to use**

Your doctor will tell you how much Fucidin H cream to use.

The usual treatment time is up to 2 weeks. Ask your doctor before using this medicine for any longer.

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 go back 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 dressings or bandages you may not need to use the medicine so often. A nappy on a baby may act as a dressing. Follow the advice of your doctor.

**Adults and children:**

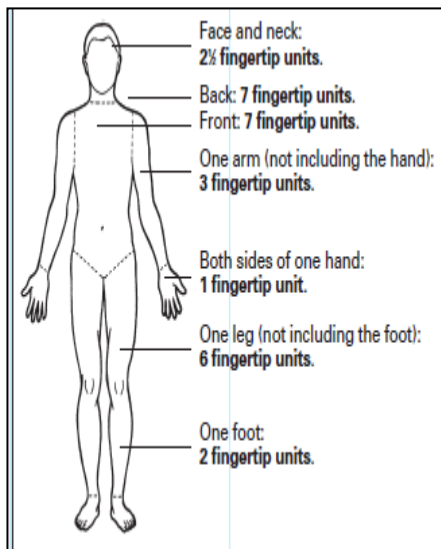
Your doctor should tell you the dose that is right for you or the child. If your doctor has told you the amount of cream to use then keep to this advice. If not, the following guide will help you to use the correct amount.

You can use your first (index) finger to measure how much Fucidin H cream to use. Squeeze the cream along your finger from the tip to the first joint as shown in the diagram. This is called a fingertip unit.



The usual number of finger tip units you need to cover different parts of the body is shown in the diagrams. If you need to use a little more or a little less do not worry. If you are using the cream on a child still use an adult finger to measure out the fingertip unit.

**For an adult:**



**For a child under 11 years:**

	Face and neck	Arm and hand	Leg and foot	Front	Back incl. buttocks
<b>Child's age</b>	<b>Number of fingertip units needed</b>				
3-6 months	1	1	1½	1	1½
1-2 years	1½	1½	2	2	3
3-5 years	1½	2	3	3	3½
6-10 years	2	2½	4½	3½	5

**If you forget to use Fucidin H cream**

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

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

**4. Possible side effects**

Like all medicines, Fucidin H cream can cause side effects, although not everybody gets them.

**Important side effects to look out for:**

**You must get urgent medical help if you have any of the following symptoms. You may be having an allergic reaction:**

- **You have difficulty breathing**
- **Your face or throat swell**
- **Your skin develops a severe rash.**

**Other possible side effects:**

Any of the problems listed below are more likely if the medicine is used for a long time, in large amounts or on skin folds (such as armpits or under breasts).

These problems are more likely in babies and children. They are also more likely if the skin is covered with a dressing, bandage or nappy.

**Skin problems****Common side effects (may affect up to 1 in 10 people)**

- Application site reaction (including itching, burning and irritation).

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

- Itchy rash and skin inflammation in the area where the medicine is used
- Worsening of your eczema
- Skin rash.

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

- Blurred vision.

Some side effects are known to be caused by hydrocortisone (steroid), one of the ingredients in Fucidin H cream. You should tell your doctor if any of the 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

- Skin redness
- Lightening of your skin colour
- Changes in the growth of your body hair
- Excessive sweating
- Steroid withdrawal reaction:

If used over prolonged periods a withdrawal reaction, which might appear to be different from the previous condition may occur in some patients during treatment or within days to weeks after on stopping treatment with some or all of the following features: 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.

### **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 Yellow Card Scheme at: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store.

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

### **5. How to store Fucidin® H cream**

- Keep out of the sight and the reach of children.
- Do not use Fucidin H cream after the expiry date which is stated on the carton after EXP. The expiry date is the last day of that month.
- Do not store above 30°C.
- The tube should be discarded 3 months after first opening. Write the date you first opened the tube in the space provided on the carton.

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 H cream contains**

- There are 2 active ingredients, fusidic acid and hydrocortisone acetate. Fucidin H cream contains 2% fusidic acid and 1% hydrocortisone.
- The other ingredients are butylhydroxyanisole (E320), cetyl alcohol, glycerol, liquid paraffin, potassium sorbate, polysorbate 60, all-rac- $\alpha$ -tocopherol, water and white soft paraffin.

You can find important information about some of the ingredients in your medicine near the end of section 2 of this leaflet.

#### **What Fucidin H cream looks like and contents of the pack**

Fucidin H cream is a white cream.

Fucidin H cream comes in tubes of 3 g, 5 g, 10 g, 15 g, 25 g, 30 g and 60 g. Not all pack sizes may be marketed.

#### **Marketing Authorisation Holder and Manufacturer**

Marketing Authorisation Holder: LEO Laboratories Limited, Maidenhead, Berkshire SL6 3UD, UK

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