

PACKAGE LEAFLET: INFORMATION FOR THE USER

Fucidin® H 20 mg/g + 10 mg/g cream
Fusidic acid/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 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.

What is in this leaflet

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1. What Fucidin® H cream is and what it is used for

Fucidin® H cream contains two 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). The two medicines work at the same time in different ways.

Fucidin® H cream works by:

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

It is used to treat:

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

2. What you need to know before you use Fucidin® H cream

Do not use Fucidin® H cream:

If you are allergic (hypersensitive) to fusidic acid/sodium fusidate or hydrocortisone acetate or any other ingredients of this medicine (listed in section 6).

As this medicine contains a steroid do not use

- To treat skin conditions caused by a fungus, such as athlete's foot or ringworm
- To treat skin conditions caused by a virus, such as cold sores or chicken pox
- To treat skin conditions caused only by bacteria, such as boils or spots
- To treat skin conditions caused by tuberculosis (TB)
- To treat a condition called perioral dermatitis. This is a red spotty rash around your mouth or chin
- To treat a skin condition called rosacea. This is redness and inflammation over your nose and cheeks. Ask your doctor if you are unsure.

Warnings and Precautions:

Talk to your doctor or pharmacist before and during use of Fucidin® H cream

- Do not use for a long time, continuously (without stopping), as this medicine contains a steroid. Do not use the cream on yourself or a child for more than 2 weeks, this is to avoid bacteria becoming resistant to the antibiotic and to avoid the steroid causing you side effects e.g. your skin may become thin.
- Do not use the cream on large areas of your body.
- Do not use the cream under bandages or dressings (as this increases the action of steroids).
- Avoid getting the cream in or near your eyes (e.g. accidentally from your hands) as it could damage them or cause an increased pressure in your eyes.
- Contact your doctor if you experience blurred vision or other visual disturbances.
- Do not use a large amount of the cream (follow your doctor's instructions). Do not use the cream on thinning skin, skin ulcers, acne (spots) or in skin folds (e.g. under breasts, groin area or armpits).

Other medicines and Fucidin® H cream

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

Pregnancy and breast-feeding

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.

- If you are pregnant or think you might be pregnant; Fucidin® H cream should not be used during pregnancy unless you are told to do so by your doctor.
- If you are breast-feeding; Fucidin® H cream may be used by women who are breast-feeding but the cream should not be applied to the breast.

Driving and using machines

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

Fucidin® H cream contains

- Butylhydroxyanisole (E320). This may cause an itchy red rash with heat and swelling on your skin where the cream is used (e.g. contact dermatitis). It may also cause irritation to the eyes and mucous membranes (e.g. mouth, nose and ears).
- Cetyl alcohol. This may give you an itchy red rash with swelling on your skin where the cream is used (e.g. contact dermatitis).
- Potassium sorbate. This may give you an itchy red rash and inflammation on your skin where the cream is used (e.g. contact dermatitis).

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

3. How to use Fucidin® H cream

Always use this medicine 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.

Always wash your hands before using Fucidin® H cream.

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 in the tube.

Rub the cream gently on the skin. If your doctor has told you to use it on your face be very careful to avoid your eyes. 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.

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

How much Fucidin® H cream to use

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

The usual treatment time is about two 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 seven days you should stop using the cream and go back to your doctor.

Usually you should use this cream 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 e.g. a nappy on a baby may act as a dressing. Follow the advice of your doctor.

Use in children

Do not use this medicine on a child for more than 2 weeks as it contains steroids.

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 about using this medicine, please ask your doctor or pharmacist.

What medical checks will you have?

Normally no special medical checks are needed if the cream is used as intended.

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.

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 lips and mouth start to tingle or swell**
- **Your face or throat swell**
- **Your skin develops a severe rash.**

Other possible effects:

Other possible side effects which are less serious can also occur. You should tell your doctor about these as soon as possible.

Common (may affect up to 1 in 10 people)

- Itching, burning or skin irritation in the area you have used the cream.

Uncommon (may affect up to 1 in 100 people)

- Itchy rash and skin inflammation in the area where the medicine is used (contact dermatitis)
- Worsening of eczema
- Rash.

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

- Blurred vision.

The following side effects are known to be caused by all steroids and are more likely to occur after using steroids for a long time:

- Your adrenal glands may stop working properly. Signs are tiredness, depression and anxiety
- An increase in pressure inside the eye (signs are eye pain, red eye, decreased or cloudy vision)
- Thinning of skin
- Skin rash with inflammation or swelling (contact dermatitis) or with pimples like acne
- Red rash around the mouth (perioral dermatitis)
- Appearance of surface veins or stretch marks
- Redness and inflammation over your nose and cheeks (rosacea)
- Redness
- Lightening of skin colour in the area you have used the cream (depigmentation)
- Increased hair growth on the body
- You may sweat more
- Red blood spots under your skin.

If any of the side effects become serious or if you notice any side effects not listed here, please tell your doctor or pharmacist as soon as possible.

If you get any side effects, talk to your doctor or pharmacist. This includes any side effects not listed in this leaflet.

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 to the national reporting system via HPRA Pharmacovigilance, Earlsfort Terrace, IRL-Dublin 2. Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; e-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Fucidin® H 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 tube or carton after EXP. This expiry date refers to 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

- The two active substances are fusidic acid and hydrocortisone acetate. 1 gram of Fucidin® H contains 20 mg of fusidic acid and 10 mg of hydrocortisone acetate.
- The other ingredients are butylhydroxyanisole (E320), cetyl alcohol, glycerol, liquid paraffin, potassium sorbate, polysorbate 60, white soft paraffin, all-*rac*- α -tocopherol, purified water and hydrochloric acid for pH adjustment.

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. It comes in tubes of 5 g, 15 g and 30 g. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturers:

Marketing Authorisation Holder and Manufacturer:

LEO Laboratories Limited, Cashel Road, Dublin 12

Manufacturer:

LEO Pharma Manufacturing Italy S.r.l
Via E. Schering 21
20054 Segrate (MI)
Italy

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