

Fucidin® H 20 mg/g + 10 mg/g cream

fusidic acid/hydrocortisone acetate

Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This cream 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 any of the side effects become serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Fucidin® H cream is and what it is used for
2. Before you use Fucidin® H cream
3. How to use Fucidin® H cream
4. Possible side effects
5. How to store Fucidin® H cream
6. Further information

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.

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. BEFORE YOU USE FUCIDIN® 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 ingredients in your medicine. You will find a list of these ingredients in section 6 of this leaflet.
- To treat a skin condition called rosacea. This is redness and spots on your nose and cheeks. Ask your doctor if you are unsure.
- To treat a condition called perioral dermatitis. This is a red spotty rash around your mouth or chin.
- To treat conditions caused only by bacteria, such as boils or spots.
- To treat skin conditions caused by viruses, such as cold sores or chicken pox.
- To treat skin conditions caused by a fungus, such as athlete's foot or ringworm.
- To treat skin conditions caused by tuberculosis (TB) or syphilis.

! Take special care with Fucidin® H cream:

- Do not use the cream for a long time as the germs (bacteria) may no longer be killed by the antibiotic.
- Do not use the cream on yourself or a child for more than 2 weeks.
- Do not use the cream on your face.
- Avoid getting the cream in your eyes (e.g. accidentally from your hands) as it could irritate them or cause an increased pressure in your eyes.
- Do not use the cream under bandages or dressings (as this increases the action of steroids).
- Do not use the cream on thinning skin, easily damaged veins, skin ulcers, acne (spots) or in skin folds (e.g. under breasts, groin area or armpits)
- Do not use the cream on your anus (back passage) or genitals (sex organs)
- Do not use the cream on large areas of your body.
- Do not use the cream on open wounds or mucous membranes (e.g. nose or mouth)

! Taking other medicines

Please tell your doctor or pharmacist if you are taking, or have recently taken any other medicines.

This includes medicines you have bought without a prescription or herbal 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 might be pregnant.
- If you are breast-feeding. Fucidin® H cream can be used during breast-feeding. However, if used on the nipples the cream should be cleaned off before breast-feeding.

Tell your 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 machinery. Check with your doctor if you feel any side effect that may stop you from driving or using machinery.

Important information about some of the ingredients of Fucidin® H cream

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 with heat and swelling on your skin where the cream is used (e.g. contact dermatitis).

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

3. HOW TO USE FUCIDIN® H CREAM

Always use Fucidin® H cream exactly as your doctor has told you. You should 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 in 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.

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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 improving 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.

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 about the use of this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Fucidin® H cream can cause side effects, although not everybody gets them. In clinical trials, approximately 5 out of every 100 patients got a side effect.

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. How often this can happen is not known exactly, but it has been reported.

- 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:

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 children. They are also more likely if the skin is covered with a dressing, bandage or nappy.

Uncommon (probably affects up to 1 in 100 people)

- Itchy skin
- Worsening of eczema
- Skin irritation
- Burning or stinging sensation

Frequency Unknown (how often these happen is not known):

- Rash
- Itchy, red rash with heat or swelling (allergic contact dermatitis)
- Lightening of skin colour in the area you have used the cream (depigmentation)

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:

- Thinning of the skin
- Appearance of surface veins or stretch marks
- Redness or swelling of hair roots
- Increased hair growth on parts of the body
- Red spotty rash around the mouth or chin (perioral dermatitis)
- Itchy red rash with heat or swelling (allergic contact dermatitis)
- Your adrenal glands may stop working properly. Signs are tiredness, depression and anxiety

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.

5. HOW TO STORE FUCIDIN® H CREAM

- Store in a safe place out of the reach and sight of children.
- Do not store above 30°C.
- Do not use the cream after the expiry date stated on the tube or carton (EXP). This expiry date refers to the last day of that month.

Do not dispose of medicines via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Fucidin® H cream contains

- There are two active ingredients, 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

Fucidin® H cream is a white coloured cream. It comes in tubes of 5 g, 15 g and 30 g. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder and Manufacturer:

LEO Laboratories Limited,
Cashel Road, Dublin 12

For further information about this product contact the local representative of the marketing authorisation holder:

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