

FUCIDIN[®] H CREAM

Fusidic acid / Hydrocortisone acetate (20mg/g / 10 mg/g)

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What Fucidin[®] H Cream is used for

It is used for the topical treatment of infected atopic dermatitis (commonly known as eczema, a skin disease accompanied by inflammation reddening, exudation or scabs and itching, frequently of an allergic origin).

You must talk to a doctor if you do not feel better or if you feel worse.

How Fucidin[®] H Cream works

Fucidin[®] H Cream combines the antibacterial action of Fusidic acid (antibiotic) with the anti-inflammatory effect of hydrocortisone acetate (corticoid).

Before you use Fucidin[®] H Cream

- When you must not use it

Do not use Fucidin[®] H Cream

- If your intention is to treat skin conditions caused by tuberculosis
- If you are allergic to fusidic acid, hydrocortisone acetate or any of the other ingredients of Fucidin[®] H Cream.
- If you have a skin infection primarily caused by bacteria,

fungi or virus (such as herpes or varicella).

- If you have skin inflammation around the mouth.
- If you have rosacea (severe flushing of the skin on the face).

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.

Use during pregnancy and lactation should be evaluated and decided upon by a doctor.

Fucidin[®] H Cream should be used with caution during pregnancy.

- There is inadequate evidence of safety in human pregnancy. Safety in mothers has not been established. Topical corticosteroids should not be applied to the breast prior to nursing.

- Before you start to use it

Take special care with Fucidin[®] H Cream

Talk to your doctor or pharmacist before using Fucidin[®] H Cream

- Fucidin[®] H Cream should be applied with care when used near the eyes. Fucidin[®] H must not enter the eyes.

Children

Fucidin[®] H Cream should be used with care in children.

- *Taking other medicines*

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

Important information about some of the ingredients of Fucidin[®] H Cream

Fucidin[®] H Cream contains Butylhydroxyanisole (E320), cetyl alcohol and potassium sorbate (E202). These ingredients may cause local skin reactions (e.g. contact dermatitis). Butylhydroxyanisole may also cause irritation to the eyes and mucous membranes (such as nasal passages and lips)

How to use Fucidin[®] H Cream

- How much to use

The recommended dose for children, adolescents and adults is:

- Carefully apply a thin layer of cream to the affected area of the skin, three times daily.

Wash your hands carefully after applying this medicine, unless your hands are the area being treated

- When to use it

- Always use this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

- How long to use it

- This medicine should not be used for more than 7 days in the absence of any clinical improvement.

- If you forget to use it

- In case you forget to apply the cream at your regular time, apply it as soon as possible and continue as usual.

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- If you use too much (overdose)

- If you have applied more cream than you should, consult your doctor or pharmacist.

While you are using it

- Things you must do

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are taking Fucidin[®] H Cream.

Tell your doctor immediately if you become pregnant while taking this medication.

- Things you must not do

Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor.

Do not give Fucidin[®] H Cream to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

- Long-term continuous therapy should be avoided in infants as adrenal insufficiency (impaired hormone production by adrenal gland) may occur.
- Doping test: Athletes are not allowed to use corticosteroids, except for locally used cream/ointment/solution containing steroids. If such a cream/ointment/solution is used, the athlete is to write a notification (Medical Certificate) about this before the contest start.

Driving and using machines

The treatment with Fucidin[®] H Cream should not affect the ability to drive and use machines.

Side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Common side effects (affects 1 to 10 users in 100)

- reaction at the application site (e.g. skin irritation, skin burning or itching)

Uncommon (affects less than 1 in 100 people)

- hypersensitivity
- skin inflammation due to contact aggravation of eczema
- rash

Other side effects caused by prolonged treatment of mild corticoids like hydrocortisone include:

- thinning of the skin (skin atrophy)
- dermatitis
- stretch marks (striae)
- dilatation of the small blood vessels on the skin
- persistent facial redness (rosacea)
- redness of the skin (erythema)
- depigmentation
- excessive growth of the hair (hypertrichosis)
- excessive sweating (hyperhidrosis)
- bruises
- signs of tiredness, depression and anxiety due to adrenal insufficiency which causes adrenal gland to stop working properly.
- complications may arise if administered too close to the eye (i.e. raised intra-ocular pressure and glaucoma)

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

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website npra.moh.gov.my (Public → Reporting Medicinal Problems / Side Effects / AEFI / Vaccine Safety).

Storage and Disposal of Fucidin[®] H Cream

- Storage

- Keep out of the reach and sight of children.
- Do not use after the expiry date, which is stated on the label after

EXP. This expiry date refers to the last day of that month.

- To be stored up to 3 years at controlled room temperatures (15°C - 25°C).

- Disposal

Do not throw away any 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.

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Product Description

- What it looks like
Fucidin[®] H is a white cream.

Each package contains a tube with 5 or 15 grams of cream.

Not all pack sizes may be marketed

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- *Ingredients*

- The active substances are fusidic acid and hydrocortisone acetate. Each gram of cream contains 20 mg of fusidic acid and 10 mg of hydrocortisone acetate.

- The inactive ingredients are butylhydroxyanisole (E320), cetyl alcohol, glycerol (85 per cent), liquid paraffin, polysorbate, potassium sorbate (E202), polysorbate 60, white soft paraffin, and purified water.

- *MAL number:*

MAL20001028AZ

Manufacturer

LEO Laboratories Ltd
285, Cashel Road, Crumlin, Dublin 12,
Ireland

Product Registration Holder

DKSH Malaysia Sdn Bhd
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