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**READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE
PATIENT MEDICATION INFORMATION**

**FUCIDIN® H
Fusidic acid and Hydrocortisone acetate 2% / 1% Cream**

Read this carefully before you start taking **FUCIDIN® H Cream** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **FUCIDIN® H Cream**.

What is FUCIDIN® H Cream used for?

FUCIDIN® H Cream is used to treat atopic dermatitis (eczema), a condition where the skin is red, swollen, itchy and infected by germs (bacteria).

Antibacterial drugs like FUCIDIN® H Cream treat only bacterial infections. They do not treat viral infections. Although you may feel better early in your treatment, FUCIDIN® H Cream should be used exactly as directed. Misuse or overuse of FUCIDIN® H Cream could lead to the growth of bacteria that will not be killed by FUCIDIN® H Cream (resistance). This means that FUCIDIN® H Cream may not work for you in the future. Do not share your medicine.

How does FUCIDIN® H Cream work?

FUCIDIN® H Cream contains 2 medicines that work together in different ways:

- fusidic acid: an antibiotic that kills bacteria.
- hydrocortisone acetate: a corticosteroid that reduces swelling, redness, pain and itchiness in the skin.

What are the ingredients in FUCIDIN® H Cream?

Medicinal ingredients: 2% fusidic acid (hemihydrate) and 1% hydrocortisone acetate.
Non-medicinal ingredients: butylated hydroxyanisole, cetyl alcohol, glycerol (85%), liquid paraffin, potassium sorbate, polysorbate 60, white soft paraffin and purified water.

FUCIDIN® H Cream comes in the following dosage forms:

FUCIDIN® H is a white cream.

Do not use FUCIDIN® H Cream if:

- you are allergic to any of the ingredients in FUCIDIN H or the container (aluminium).
- you have skin infections caused by a fungus, such as athlete's foot, ringworm.
- you have skin conditions caused by virus such as cold sores or chicken pox.
- you have skin conditions caused by tuberculosis.
- you have skin rashes following vaccinations.
- you have skin condition called perioral dermatitis.

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- you have a skin condition called rosacea.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take FUCIDIN® H Cream. Talk about any health conditions or problems you may have, including if you:

- are pregnant or if you become pregnant during treatment with FUCIDIN® H Cream.
- are breastfeeding or intend to breastfeed.

Other warnings you should know about:

- Do not use Fucidin® H Cream over a long time (more than 14 days).
- Use Fucidin® H Cream exactly as directed. Do not apply more or less of it or apply it more often than prescribed by your doctor. If you misuse or overuse FUCIDIN® H Cream your infection may not be completely cured and the bacteria may become resistant to antibiotics.
- Do not apply it on broken or damaged skin or sensitive skin areas such as lips or genital area, except on the advice of a doctor.
- Do not wrap or bandage the treated area, except on the advice of a doctor.
- If you use Fucidin® H Cream in large amounts, it may make the chance of getting any side effects higher. Also, your skin may get more sensitive to this medicine.
- Do not let FUCIDIN® H get into your eyes. If the cream gets into the eye, this may lead to glaucoma or other eyes conditions.
- Fucidin® H Cream contains butyl hydroxyanisole, cetyl alcohol and potassium sorbate as non-medicinal ingredients. These ingredients may cause a red, itchy rash (Contact dermatitis) on your skin where Fucidin® H Cream is applied. Butyl hydroxyl-anisole may also cause irritation to the eyes and mucous membranes (such as lips or genital area).

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with FUCIDIN® H Cream:

The use of FUCIDIN® H Cream with other medicines has not been studied. However, since medicines can interact with each other, tell your healthcare professional if you are using other medicines to treat your atopic dermatitis. In particular, tell them if you are using medicines that contain corticosteroids.

How to take FUCIDIN® H Cream:

Adults and children 3 years of age and older:

Apply the cream to the affected areas 3 times per day for a maximum of 2 weeks.

Overdose:

In case of drug overdose or accidental swallowing of FUCIDIN® H Cream, contact your healthcare professional, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.
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Missed Dose:

If you forget to use FUCIDIN® H Cream, use it as soon as you remember. Next time, follow your

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regular application routine.

What are possible side effects from using FUCIDIN® H Cream?

These are not all the possible side effects you may feel when taking FUCIDIN® H Cream. If you experience any side effects not listed here, contact your healthcare professional. Please also see Warnings and Precautions.

Side effects from using FUCIDIN® H Cream may include:

- itching, burning or irritation in the area where the medication is used
- various types of skin rashes (dermatitis) in the area where the medication is used
- thinning skin, stretch marks or surface veins
- skin redness
- lightening of your skin colour
- changes in the growth of your body hair
- excessive sweating

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
UNCOMMON Allergic reactions: dizziness, itching, severe rash, swelling (mouth, throat, lips, hands), trouble breathing.			✓
Worsening of eczema: increased itching, redness and swelling.		✓	
RARE Adrenal effects: fatigue, increased urination/thirst, problems controlling blood sugar levels, weakness, weight loss, delayed weight gain and slow growth in children.		✓	
Glaucoma: hazy or blurred vision, severe eye and head pain, nausea or vomiting (accompanying severe eye pain), sudden sight loss.		✓	

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

Store below 30°C. Use within 3 months of first opening the tube.

Keep out of reach and sight of children and pets.

If you want more information about FUCIDIN® H Cream:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the manufacturer's website www.leo-pharma.ca, or by calling 1-800-668-7234.

This leaflet was prepared by LEO Pharma Inc.

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