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

FUCIDIN[®] Fusidic acid, 2% Cream Sodium Fusidate, 2% Ointment

Read this carefully before you start taking **FUCIDIN**[®] 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**[®].

What is FUCIDIN[®] used for?

FUCIDIN[®] is used to treat conditions where the skin is infected by germs (bacteria), such as:

- Impetigo (a weeping, crusty and swollen patch of skin)
- Erythrasma (brown, scaly patches of skin, usually in skin fold areas, such as armpits or under breasts)
- Infected cuts and burns

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

How does FUCIDIN[®] work?

FUCIDIN[®] Cream contains fusidic acid. FUCIDIN[®] Ointment contains sodium fusidate. Both medicines are antibiotics which are used to kill bacteria that cause infections.

What are the ingredients in FUCIDIN[®]?

Medicinal ingredients:FUCIDIN® Cream – 2% fusidic acid (hemihydrate)
FUCIDIN® Ointment – 2% sodium fusidateNon-medicinal ingredients:FUCIDIN® Cream – all-rac-α-tocopherol, butylhydroxyanisole
(E320), cetyl alcohol, glycerol (85%), hydrochloric acid, white soft
paraffin, liquid paraffin, polysorbate 60, potassium sorbate,
purified water.FUCIDIN® Ointment – all-rac-α-tocopherol, butylhydroxytoluene
(E321), cetyl alcohol, white soft paraffin, liquid paraffin, wool fat
(lanolin).

FUCIDIN[®] comes in the following dosage forms:

FUCIDIN[®] Cream is a white to off-white cream. FUCIDIN[®] Ointment is a translucent vellowish to white ointment.

Do not use FUCIDIN[®] if:

• you are allergic to any ingredient in FUCIDIN[®] Cream or Ointment or to any component

of the container.

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

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

Other warnings you should know about:

- Do not use Fucidin[®] Cream or Ointment more than 14 days.
- If you use Fucidin[®] Cream or Ointment more than 14 days the bacteria may become resistant to antibiotics.
- Fucidin[®] Cream contains butylhydroxyanisole, cetyl alcohol and potassium sorbate as non-medicinal ingredients. These ingredients may cause a red, itchy rash (contact dermatitis) on your skin where Fucidin[®] Cream is applied. Butylhydroxyanisole may also cause irritation to the eyes and mucous membranes (such as lips or genital area).
- Fucidin[®] Ointment contains cetyl alcohol, hydrous lanolin and butylhydroxytoluene (E321) as non-medicinal ingredients. These ingredients may cause a red, itchy rash (contact dermatitis) on your skin where Fucidin[®] Ointment is applied. Butylhydroxytoluene (E321) may also cause irritation to the eyes and mucous membranes (such as lips or genital area).
- Do not let FUCIDIN[®] get into your eyes. If the cream or the ointment gets into the eye, this may lead to eye irritation.

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[®]:

The use of FUCIDIN[®] 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 skin infection.

How to take FUCIDIN[®]:

Usual dose:

- Without a covering dressing: apply a small amount of FUCIDIN[®] Cream or Ointment to the affected area two to three times daily for 7-14 days.
- With a covering dressing: one or two application daily may be enough.

It is not necessary to remove any crusts caused by impetigo before applying FUCIDIN[®]. Use Fucidin[®] exactly as directed. Do not apply more or less of it or apply it more often than prescribed by your healthcare professional.

Overdose:

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

Missed Dose:

If you forget to use FUCIDIN[®], use it as soon as you remember. Next time, follow your regular application routine.

What are possible side effects from using FUCIDIN[®]?

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

Side effects from using FUCIDIN[®] may include:

- itching, burning sensation, irritation or pain in the area where the medication is used
- various types of skin rashes (dermatitis)
- Skin redness
- Blistering of the skin
- Hives also known as urticaria (a skin reaction that causes itchy welts)

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and
	Only if severe	In all cases	get immediate medical help
RAREAllergic reactions (angioedema):dizziness, itching, severe rash,swelling (mouth, throat, lips,hands), trouble breathing			∠
Conjunctivitis: pink or red colour in the white of the eye(s), watery eyes, itchy or scratchy eyes, discharge from the eye(s), crusts on the eyelids or lashes		1	

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/medeffectcanada/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:

FUCIDIN CREAM: Store below 30 ℃. FUCIDIN OINTMENT: Store below 30 ℃. 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[®]:

- 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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