

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

PRFUCIBET®
Fusidic acid and Betamethasone valerate

Read this carefully before you start taking Fucibet® 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 Fucibet®.

What is Fucibet® used for?

Eczema or dermatitis is an irritated skin condition that comes and goes. The skin is red, itchy, inflamed and may have oozing blisters or crusting. Eczema lesions can get infected when the skin cracks or splits. Fucibet® is used to treat eczema that is infected with bacteria or appears to be infected.

Fucibet® contains an antibiotic called fusidic acid. Use Fucibet® exactly as your healthcare professional tells you. Using Fucibet® incorrectly or using too much could lead to the growth of bacteria that cannot be killed by this medicine. If this happens, Fucibet® or other medicines with fusidic acid may not work for you in the future. Do not share this medicine.

How does Fucibet® work?

Fucibet® contains two medicines that work together in different ways:

- Fusidic acid is an antibiotic that kills bacteria.
- Betamethasone is a steroid that reduces swelling, redness, pain and itchiness in the skin.

What are the ingredients in Fucibet®?

Medicinal ingredients: fusidic acid and betamethasone valerate

Non-medicinal ingredients: all- *rac-α*-tocopherol, cetostearyl alcohol, citric acid monohydrate, hypromellose, liquid paraffin, methyl parahydroxybenzoate, potassium sorbate, propyl parahydroxybenzoate, purified water, steareth-21 and white soft paraffin.

Fucibet® comes in the following dosage forms:

Fucibet® is a white cream containing 2% fusidic acid and 0.1% betamethasone (as valerate). The high lipid content in this cream helps relieve the dry feeling of the skin.

Do not use Fucibet® if:

- You are allergic to any of the ingredients in Fucibet® (see above) or the materials of the container.

Do not use to treat an area of skin where:

- You have a fungal infection (such as athlete's foot or ringworm)
- You have a skin infection not related to your eczema caused by a virus or bacteria
- You have a skin condition related to tuberculosis or syphilis
- You have perioral dermatitis (rash around the mouth) and rosacea (red flushed facial skin).
- You have a rash on the skin where you received a vaccination

To help avoid side effects and ensure proper use, talk to your healthcare professional

before you use Fucibet®. Talk about any health conditions or problems you may have, including if:

- Your infection or eczema gets worse, you get new infected lesions, or you have any other skin reactions
- You use other medicines that contain steroids
- You are pregnant or planning to get pregnant
- You are breast-feeding or plan to breast-feed

Other warnings you should know about:

- Use with care around the eye area. Avoid getting Fucibet® in your eyes
- Using Fucibet® near the eye area may cause glaucoma (increased pressure in your eye) or cataracts (clouding of the lens of your eye). See table of “Serious side effects and what to do about them” below
- Using Fucibet® for more than 2 weeks or in large amounts, may increase your chance of experiencing side effects.
- Do not wrap or bandage the area treated by Fucibet®
- Fucibet® contains methyl and propyl parahydroxybenzoate, cetyl alcohol and potassium sorbate. These ingredients may cause a red, itchy rash (contact dermatitis) on your skin where Fucibet® is applied or cause allergic reactions. Talk to your doctor if you experience any of these side effects while using Fucibet®.

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 Fucibet®:

There are no drugs known to interact with Fucibet®.

How to apply Fucibet®:

Apply a thin layer of cream to cover the affected skin area. Wash your hands after applying to avoid accidentally spreading Fucibet® to healthy skin areas.

Usual dose:

Use Fucibet® twice daily. Do not use for longer than 2 weeks.

Overdose:

Using this drug for longer than recommended can lead to medical conditions, such as Cushing’s syndrome or adrenal suppression.

Accidentally swallowing Fucibet® is not likely to lead to any serious side effects.

If you think you have taken too much Fucibet® 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 apply Fucibet®, apply it as soon as you remember. Then continue as usual for your next application.

What are possible side effects from using Fucibet®?

Common side effects are itching, skin rash (contact dermatitis), stretch marks (striae), skin

discoloration and thinning of the skin (atrophy).

Less common side effects include a burning sensation of the skin, dry skin, redness of the skin, small fluid filled blisters and pain, irritation or swelling of the treated skin area. Most side effects are mild to moderate.

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	
Allergic Reactions: Dizziness, itching, severe rash, swelling (mouth, throat, lips, hands)), trouble breathing.			X
Worsening of eczema: Increased itching, redness, swelling		X	
Adrenal effects: Fatigue, increased urination / thirst, problems controlling blood sugar levels, weakness, weight loss.		X	
Glaucoma: Hazy or blurred vision severe eye and head pain, nausea or vomiting (accompanying severe eye pain), sudden sight loss		X	
Cataracts: Clouded, blurred or dim vision.		X	

These are not all the possible side effects that you may have when using Fucibet®. 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 (<http://www.hc-sc.gc.ca/dhp-mpps/medeff/report-declaration/index-eng.php>) 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 at or below 25°C. Use within 3 months of first opening the tube and before the expiry date. Keep out of reach and sight of children.

If you want more information about Fucibet®:

- 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 (<http://hc-sc.gc.ca/index-eng.php>); 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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