

Package leaflet: Information for the user

Fucibet® 20 mg/g + 1 mg/g cream

fusidic acid/betamethasone

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.
- In this leaflet Fucibet® cream will be called Fucibet®.

What is in this leaflet:

1. What Fucibet® is and what it is used for
2. What you need to know before you use Fucibet®
3. How to use Fucibet®
4. Possible side effects
5. How to store Fucibet®
6. Contents of the pack and other information

1. What Fucibet® is and what it is used for

Fucibet® contains two different types of medicine. One medicine is called fusidic acid. It is a type of antibiotic. The other medicine is called betamethasone valerate. It is a type of corticosteroid (steroid). The two medicines work at the same time in different ways.

Fucibet® works by:

- The antibiotic killing germs (bacteria) that cause infections.
- The corticosteroid reducing any swelling, redness or itchiness of your skin.

Fucibet® is used to treat:

- Conditions where the skin is inflamed (eczema or dermatitis) and infected, or might become infected, by germs (bacteria).

2. What you need to know before you use Fucibet®

Do not use Fucibet®

- If you are allergic (hypersensitive) to fusidic acid/sodium fusidate or betamethasone valerate or any of the other ingredients of this medicine (listed in section 6).
- To treat infections caused by a fungus, such as athlete's foot or ringworm
- To treat a skin condition caused by a virus, such as cold sores or chicken pox
- To treat skin conditions caused only by bacteria, such as boils or spots
- To treat skin conditions caused by tuberculosis (TB)
- To treat a condition called perioral dermatitis. This is a red spotty rash around your mouth or chin.
- To treat a skin condition called rosacea. This is redness and inflammation over your nose and cheeks. Ask your doctor if you are unsure.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before and during use of Fucibet®:

- Do not use for a long time, continuously (without stopping), as this medicine contains a steroid. Do not use the cream on yourself or a child for more than 2 weeks, this is to avoid bacteria becoming resistant to the antibiotic and to avoid the steroid causing you side effects.
- Avoid getting the cream in or near your eyes (e.g. accidentally from your hands) as it could damage them
- Contact your doctor if you experience blurred vision or other visual disturbances.
- Do not use a large amount of the cream (follow your doctor's instructions). Do not use the cream on thinning skin, skin ulcers, acne (spots) or in skin folds (e.g. under breasts, groin area or armpits).
- Do not use the cream under bandages or dressings (as this increases the action of steroids)
- Take special care if you are going to use this medicine on a child, as children are more sensitive to steroids.

- Take care if you have been or are susceptible to infections.

Other medicines and Fucibet®

Tell your doctor or pharmacist if you are using have recently used or might use any other medicines.

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.

- If you are pregnant or think you might be pregnant, Fucibet® cream should not be used during pregnancy unless you are told to do so by your doctor.
- if you are breast-feeding. Fucibet® cream may be used by women who are breast-feeding, but the cream should not be applied to the breast.

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.

Fucibet® contains

- Cetostearyl alcohol. This may give you an itchy red rash with heat and swelling on your skin where the cream is used (e.g. contact dermatitis)
- Chlorocresol. This may give you an allergic reaction. This may happen at any time after you use your medicine. Please read section 4 so you can spot any signs that this may be happening to you.
Please ask your doctor or pharmacist if you are worried about any of the ingredients in this medicine.

3. How to use Fucibet®

Always use this medicine exactly as your doctor has told you.

Check with your doctor or pharmacist if you are not sure.

How to put on Fucibet®

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 Fucibet®.

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 with 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 Fucibet®.

How much Fucibet® to use

Your doctor will tell you how much Fucibet® to use.

The usual treatment time is up to two weeks. Ask your doctor before using this medicine for any longer.

You should notice your skin improve 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.

HOW MUCH CREAM SHOULD I USE?

If your doctor has given you specific instructions about the amount of cream to use, then keep to this advice. If not, the following guide will help you to use the correct amount.

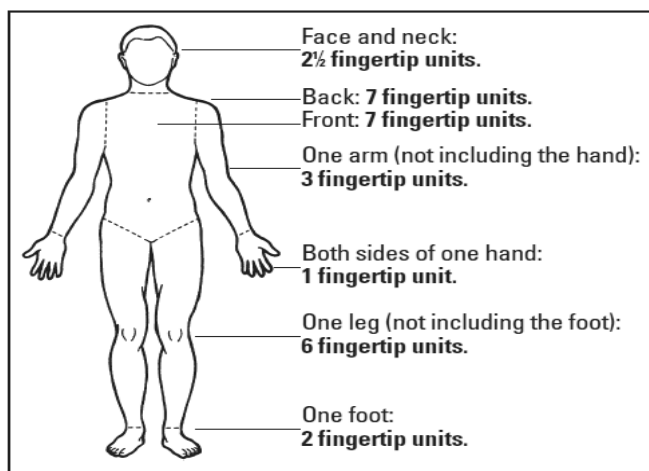
Use your index finger (first finger) as a measure. Squeeze the cream from the tube along your index finger from the tip to the first joint as shown in the diagram on the right. This amount of cream is one fingertip unit. One fingertip unit is the amount of cream squeezed along your index finger to the first joint.



For adults

The diagram below shows how much cream you need to cover different areas of your body.

If you find you need slightly more or less cream than indicated, do not worry as this is only a general guide.



Use in children

- The above guide is for adult use only and is not suitable for use in children
- Do not use this medicine on a child for more than 2 weeks as it contains steroids

If you forget to use Fucibet®

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

The most common side effect is itching.

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.

- 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 side effects:

Other possible side effects which are less serious can also occur. You should tell your doctor about these as soon as possible.

Uncommon (may affect up to 1 in 100 people)

- Itchy rash and skin inflammation in the area where the medicine is used (contact dermatitis)
- Worsening of your eczema.
- Skin burning feeling
- Itchy skin
- Dry skin
- Pain or skin irritation in the area where the medicine is used,

Rare (may affect up to 1 in 1,000 people)

- Redness of the skin
- Hives
- Rash
- Swelling in the area where the medicine is used
- Redness of the skin due to widening of the small blood vessels

Frequency not known (cannot be estimated from the available data)

- Blurred vision

The following additional side effects are known to be caused by steroids and are more likely to occur after longer term use:

- Your adrenal glands may stop working properly. Signs are tiredness, depression and anxiety
- An increase in pressure inside the eye (signs are eye pain, red eye, decreased or cloudy vision) or eye cataracts (signs are cloudy or foggy vision)
- Thinning of the skin
- Skin rash with inflammation or swelling (contact dermatitis) or with pimples like acne
- Red rash around the mouth (perioral dermatitis)
- Appearance of surface veins or stretch marks
- Redness and inflammation over your nose and cheeks (rosacea)
- Redness
- Increased hair growth on the body
- Excessive sweating
- Lightening of skin colour
- Red blood spots under your skin

If you notice the above or any other changes in your health while using this medicine, tell your doctor.

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.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse.

This includes any possible side effects not listed in this leaflet. You can also report any side effects directly via HPRA

Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Fucibet®

- Keep this medicine out of the sight and reach of children.
- Do not store this medicine above 30 °C.
- Do not use this medicine after the expiry date which is stated on the carton and tube after EXP. The expiry date refers to the last day of that month.
- Discard any remaining cream 3 months after first opening. Write the date you first opened the tube in the space provided on the carton.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What Fucibet® contains

The active substances are fusidic acid and betamethasone.

- 1 gram of Fucibet® contains 20 mg of fusidic acid and 1 mg of betamethasone (as valerate).

The other ingredients are:

- macrogol cetostearyl ether, cetostearyl alcohol, chlorocresol, liquid paraffin, sodium dihydrogen phosphate, white soft paraffin, purified water, sodium hydroxide, all-rac- α -tocopherol

You can find important information about some of the ingredients in your medicine near the end of section 2 of this leaflet.

What Fucibet® looks like and contents of the pack

Fucibet® is a white to off white cream. It comes in 30 g tubes.

Manufacturer

LEO Laboratories Limited, Cashel Road, Dublin 12.

Product procured from within the EU by the Parallel Product Authorisation Holder, repackaged and distributed by:
PCO Manufacturing Ltd., Unit 10, Ashbourne Business Park, Rath, Ashbourne, Co. Meath, Ireland.

PPA Number: PPA 465/231/1

Fucibet® is a registered trademark of LEO Pharma A/S

This leaflet was last revised in July 2019