Package Leaflet: Information for the User

Fucibet® cream

fusidic acid and betamethasone valerate

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, pharmacist or nurse.
- This medicine has been prescribed for you only. 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.
- 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 2 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). These 2 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 also infected by germs (bacteria).

Corticosteroid creams, ointments and other topical preparations come in four different potencies or strengths. These are known as mild, moderately potent, potent or very potent. Healthcare professionals will usually refer to topical corticosteroid potency rather than strength. A potent or strong corticosteroid has a much stronger effect than a mild corticosteroid when using the same amount. The percentage of active ingredient that is sometimes included on product packaging does not indicate potency. Betamethasone is classed as a strong corticosteroid.
Your healthcare professional will prescribe or advise a steroid of the appropriate potency for your condition.

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

Do not use Fucibet

- If you are allergic (hypersensitive) to fusidic acid or betamethasone valerate or any of the other ingredients in your medicine. You can find a list of these ingredients in section 6 of this leaflet.
- To treat a skin condition caused by a fungus, such as athlete's foot.
- To treat a skin condition caused by a virus, such as cold sores or chickenpox.
- To treat skin conditions caused only by bacteria, such as boils or spots.
- To treat skin conditions caused by tuberculosis (TB) or syphilis.
- To treat a skin 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 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.
- Take special care if you are going to use this medicine near your eyes or the eyes of a child. If the cream gets into the eye, this may lead to glaucoma.
- Contact your doctor if you experience blurred vision or other visual disturbances.
- If you use the cream over a long time or in large amounts it may make the chance of getting any side effects or infections higher. Also your skin may get more sensitive to this medicine.
- You must not use the medicine for a long time on your face.
- Unless your doctor has told you to, you must not use Fucibet on open wounds or sensitive areas such as the nostrils, ears, lips or genitals.
- Unless your doctor has told you to, you must not use Fucibet on thin skin, skin ulcers, broken veins or acne.
- Adrenal suppression may occur. Signs are tiredness, depression and anxiety. This can be reversed by stopping Fucibet.

Do not smoke or go near naked flames – risk of severe burns. Fabric (clothing, bedding, dressings etc) that has been in contact with this product burns more easily and is a serious fire hazard. Washing clothing and bedding may reduce product build-up but not totally remove it.

If there is a worsening of your condition during use consult your prescriber – you may be experiencing an allergic reaction, have an infection or your condition requires a different treatment. If you experience a recurrence of your condition shortly after stopping treatment, within 2 weeks, do not restart using the cream without consulting your prescriber unless your prescriber has previously advised you to so. If your condition has resolved and on recurrence the redness extends beyond the initial treatment area and you experience a burning sensation, please seek medical advice before restarting treatment.

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 using this medicine.

- If you are pregnant or think you might be pregnant: Fucibet should not be used during pregnancy, unless you are told to do so by your doctor.

- If you are breast-feeding: Fucibet may be used by women who are breast-feeding, but the cream should not be applied to the breasts to avoid accidental ingestion by the infant.

Tell your doctor if you become pregnant while using this medicine.

Driving and using machines
This medicine should not have any effect on your ability to drive or use machines. Check with your doctor if you feel any side effect that may stop you from driving or using machines.

Fucibet contains
- Cetostearyl alcohol. This may give you an itchy rash and inflammation on your skin where your medicine is used.
- Chlorocresol. This is a preservative. It may give you an allergic reaction. Please read section 4 so you can spot any signs that this may be happening to you.

Please ask your doctor 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 or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

How to apply Fucibet
This medicine is only for use on your skin or the skin of a child. Do not swallow it. Do not put it inside your body.

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 on the tube.

Always wash your hands before using Fucibet. Rub the medicine gently on the skin. If you use it on your face, be careful to avoid your eyes.

Unless you are using the cream to treat your hands, always wash your hands after using Fucibet.

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.

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

The usual treatment time is up to 2 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 7 days, you should stop using the cream and go back to your doctor.

Usually you should use this medicine 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. A nappy on a baby may act as a dressing. Follow the advice of your doctor.

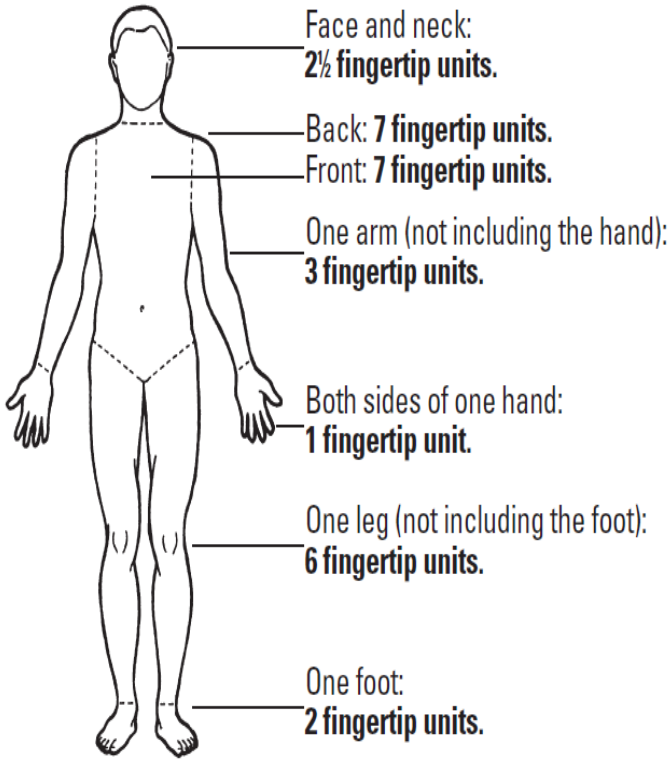
Adults and children:
Your doctor should tell you the dose that is right for you or the child. If your doctor has told you the amount of cream to use then keep to this advice. If not, the following guide will help you to use the correct amount.

You can use your first (index) finger to measure how much Fucibet to use. Squeeze the cream along your finger from the tip to the first joint as shown in the diagram. This is called a fingertip unit.

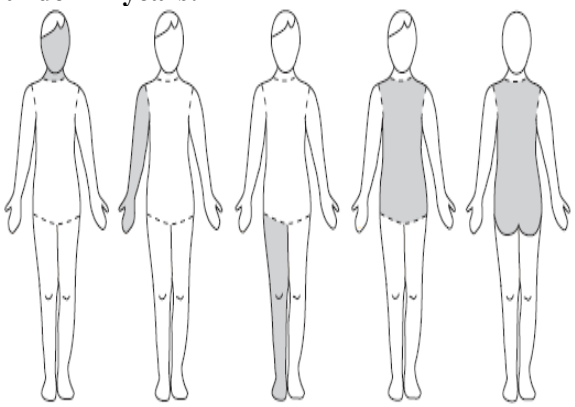


The usual number of fingertip units you need to cover different parts of the body is shown in the diagrams. If you need to use a little more or a little less do not worry. If you are using the cream on a child still use an adult finger to measure out the fingertip unit.

For an adult:



For a child under 11 years:



	Face and neck	Arm and hand	Leg and foot	Front	Back including buttocks
Child's age	Number of fingertip units needed				
3-6 months	1	1	1½	1	1½
1-2 years	1½	1½	2	2	3
3-5 years	1½	2	3	3	3½
6-10 years	2	2½	4½	3½	5

If you use more Fucibet than you should
Tell your doctor straight away if you have used more Fucibet than you should. You may need to stop using this medicine.

If you forget to use Fucibet
If you forget to use the cream at the right time, use it as soon as you remember. Then use this medicine again at the usual time.

Do not use a double dose to make up for a forgotten dose.

If you have any further questions about using this medicine, please ask your doctor or pharmacist.

4. Possible side effects

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

Important side effects to look out for:

Tell your doctor or nurse immediately if any of the following happen. You may need to stop your treatment:

- **You have difficulty breathing**
- **Your face or throat swell**
- **Your skin develops a severe rash.**

The following less serious side effects have also been reported. If any of them last a long time or cause problems, you should tell your doctor or nurse as soon as possible:

Any of the problems listed below are more likely if the medicine is used for a long time, in large amounts or on skin folds (such as armpits or under breasts).

These problems are more likely in babies and children. They are also more likely if the skin is covered with a dressing, bandage or nappy.

Uncommon (may affect up to 1 in 100 people)

- Itchy rash and skin inflammation in the area where the medicine is used
- Worsening of your eczema
- Burning feeling
- Itching
- Dry skin
- Application site pain
- Application site irritation.

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

- Skin redness
- Hives
- Skin rash
- Application site swelling
- Application site blisters.

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

- Blurred vision.

Some side effects are known to be caused by betamethasone valerate (steroid), one of the ingredients in Fucibet. You should tell your doctor if any of the side effects occur:

- Adrenal glands may stop working properly. Signs are tiredness, depression and anxiety
- Glaucoma
- Thinning of the skin
- Red spotty rash around the mouth or chin
- Stretch marks
- Small veins near the surface of the skin become visible
- Changes in growth of your body hair
- Excessive sweating
- Lightening of your skin colour
- Redness and pimples around the mouth
- Redness of the skin, nose or mouth
- Formation of cataracts.
- Steroid withdrawal reaction:

If used over prolonged periods a withdrawal reaction, which might appear to be different from the previous condition, may occur in some patients during treatment or within days to weeks after stopping treatment with some or all of the following features: redness of the skin which can extend beyond the initial area treated, a burning or stinging sensation, intense itching, peeling of the skin, oozing open sores.

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 side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. 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 use Fucibet after the expiry date which is stated on the tube or carton after EXP. The expiry date is the last day of that month.
- Do not store the medicine above 30°C.
- Do not use the tube for more than 3 months after you first open it. Make a note of 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 any medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Fucibet contains

- The active substances are fusidic acid and betamethasone valerate.
  Fucibet contains 2% fusidic acid and 0.1% betamethasone
- The other ingredients are macrogol cetostearyl ether, cetostearyl alcohol, chlorocresol, liquid paraffin, sodium dihydrogen phosphate, white soft paraffin, all-*rac*-α-tocopherol, purified water and sodium hydroxide for pH adjustment.

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 cream.
Fucibet comes in tubes of 3 g, 5 g, 10 g, 15 g, 25 g, 30 g, 50 g and 60 g.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer
Marketing Authorisation Holder:
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Manufacturers:
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