

# Fucibet® Cream

fusidic acid and betamethasone valerate

**Please read all of this leaflet carefully before you start taking this medicine.**

- 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 symptoms are the same as yours.
- If any of the side effects become serious, or you notice any side effects not listed in this leaflet please tell your doctor or pharmacist.
- In this leaflet Fucibet® Cream will be called Fucibet®.

## In this leaflet:

1. What Fucibet® is and what it is used for
2. Before you use Fucibet®
3. How to use Fucibet®
4. Possible side effects
5. How to store Fucibet®
6. Further 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). These 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 also infected by germs (bacteria).

## 2. BEFORE YOU USE FUCIBET®

### Do not use Fucibet®

- If you are allergic (hypersensitive) to fusidic acid or betamethasone valerate.
- If you are allergic (hypersensitive) to 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 called acne rosacea. This is redness and inflammation over your nose and cheeks. Ask your doctor if you are unsure.
- To treat a skin condition called perioral dermatitis. This is a red spotty rash around your mouth or chin.
- To treat skin conditions caused only by bacteria, such as boils or spots.
- To treat a skin condition caused by a virus, such as cold sores or chickenpox.
- To treat a skin condition caused by a fungus, such as athlete's foot.

### Take special care with Fucibet®

- 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.
- If you use the cream over a long time or in large amounts it may make the chance of getting any side effects 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® Cream 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® Cream on thin skin, skin ulcers, broken veins or acne.

### Taking other medicines

Please tell your doctor or pharmacist if you are taking, or have recently taken any other medicines. This includes any medicines which you have bought without a prescription.

### Pregnancy and breast-feeding

Please ask your doctor or pharmacist for advice before using Fucibet®.

- If you are pregnant, or think you are pregnant. You must not use your medicine for a long time or in large amounts. You must ask your doctor for advice.
- If you are breast-feeding.

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

### Driving and using machines

Usually your medicine will have very little 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.

### Important information about some of the ingredients of Fucibet®

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 Fucibet® exactly as your doctor has told you. You should 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. 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 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 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:

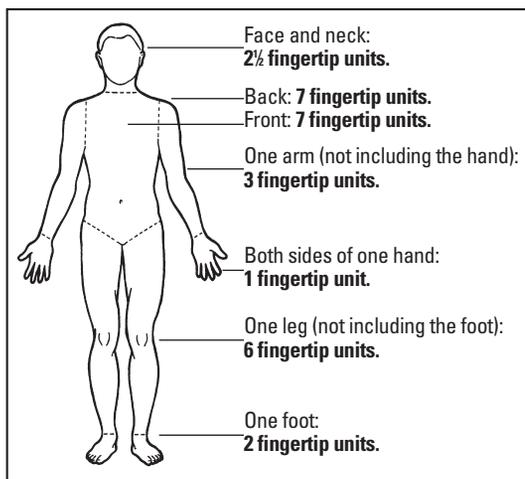
Your doctor should tell you the dose that is right for you or the child. If your doctor has told you the amount of cream to use then keep to this advice. If not, the following guide will help you to use the correct amount.

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.

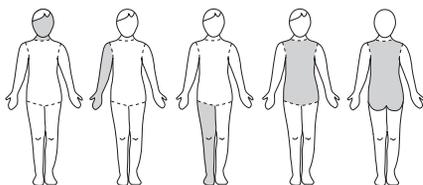


The usual number of fingertip units you need to cover different parts of the body is shown in the diagrams. If you need to use a little more or a little less do not worry. If you are using the cream on a child still use an adult finger to measure out the fingertip unit.

### For an adult:



### For a child under 11 years:



Child's age	Face and neck	Arm and hand	Leg and foot	Front	Back including buttocks
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 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.

## 4. POSSIBLE SIDE EFFECTS

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

### 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 face or throat swell
- Your skin develops a severe rash.

### Other possible side effects:

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.

### Skin problems

#### Uncommon side effects (probably affect less than 1 in 100 people)

- Skin irritation
- Burning feeling
- Itching
- Worsening of your eczema
- Stinging feeling
- Skin redness

#### Rare side effects (probably affect less than 1 in 1000 people)

- Hives
- Dry skin

#### Side effects where the number of people affected is not known:

- Itchy rash and skin inflammation in the area where the medicine is used.
- Rash
- Small veins near the surface of the skin become visible.

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

- Thinning of the skin
- Stretch marks
- Inflammation or swelling of the hair root (folliculitis)
- Changes in growth of your body hair
- Red spotty rash around the mouth or chin
- Lightening of your skin colour
- Glaucoma
- Adrenal glands may stop working properly. Signs are tiredness, depression and anxiety.

If any of the side effects become serious or you notice any side effects not listed in this leaflet, tell your doctor or pharmacist.

## 5. HOW TO STORE FUCIBET®

- Keep out of the reach and the sight of children.
- Do not use Fucibet® after the expiry date on the carton. The expiry date is the last day of that month.
- Do not keep the tube for 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 store the medicine above 30°C.

Medicines should not be thrown away in waste water or in household waste. Please ask your pharmacist how to throw away any medicine you do not need any more. If you do this you will help protect the environment.

## 6. FURTHER INFORMATION

### What Fucibet® contains

- There are two active ingredients, 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- $\alpha$ -tocopherol and purified water.

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 30g and 60g.

### Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:  
LEO Laboratories Limited, Hurley, Berkshire SL6 6RJ, UK

Manufacturer:  
LEO Laboratories Limited, Dublin 12, Ireland.

This leaflet was last revised in October 2013.

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