

PACKAGE LEAFLET: INFORMATION FOR THE USER

Fucibet® 20mg/g + 1mg/g Cream

(fusidic acid/betamethasone)

Read all of this leaflet carefully before you start using 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 if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

The name of your medicine is Fucibet 20mg/g + 1mg/g Cream but it will be referred to as Fucibet throughout the leaflet.

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). 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. 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 will find a list of these ingredients in section 6 of this leaflet.
- To treat a skin condition called rosacea. This is redness and inflammation over your nose and cheeks. Ask your doctor if you are unsure.
- To treat a 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 chicken pox.
- To treat a skin condition caused by a fungus, such as athlete's foot or ringworm.
- To treat skin conditions caused by tuberculosis (TB) or syphilis.

! Take special care with Fucibet

- Do not use the cream on yourself or a child for more than 2 weeks
- Do not use the cream on your face
- Avoid getting the cream in your eyes (e.g. accidentally from your hands) as it could damage them
- Do not use the cream under bandages or dressings (as this increases the action of steroids)
- 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 on large areas of your body
- Do not use the cream on open wounds or mucous membranes (e.g. nose or mouth)

! Taking other medicines

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

Pregnancy and breast-feeding

Please ask your doctor or pharmacist for advice before using Fucibet

- if you are pregnant or think you might be pregnant.
- if you are breast-feeding. Fucibet can be used by women who are breast-feeding, however, it should not be used directly on the breast.

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 machinery. Check with your doctor if you feel any side effect that may stop you from driving or using machinery.

Important information about some of the ingredients in Fucibet

Fucibet contains

- Cetostearyl alcohol. This may give you an itchy rash and inflammation on your skin where your medicine is used.
- 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 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.

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.

Always wash your hands before using Fucibet.

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?

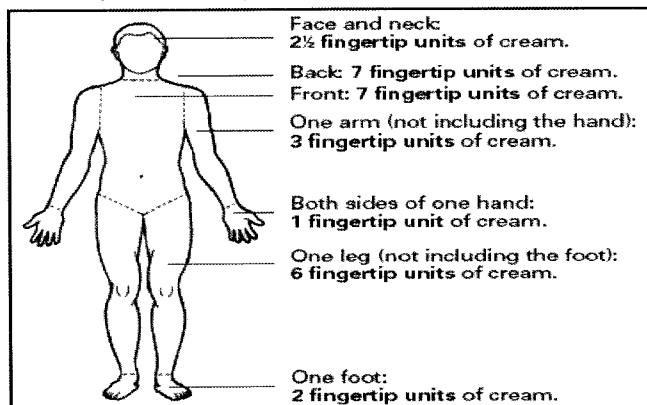
If your doctor has given you specific instructions about the amount of cream to use, then keep to this advice. If not, the following guide will help

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 left. 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 you 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.



The above guide is for adult use only and is not suitable for use in children.

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, Fucibet can cause side effects, although most people do not get them. In clinical trials 3 out of every 100 patients got a side effect.

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. This is very rare (probably affects up to 1 in 10,000 people).

- 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:

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 children. They are also more likely if the skin is covered with a dressing, bandage or nappy.

Uncommon (probably affects up to 1 in 100 people)

- Worsening of your eczema
- Nettle rash or hives
- Itchy rash and skin inflammation in the area where the medicine is used (contact dermatitis)

- Dry skin
- Rash
- Skin irritation and itch
- Burning or stinging feeling
- Redness of the skin due to widening of the small blood vessels

Very rare (probably affects up to 1 in 10,000 people)

- Thinning of the skin
- Appearance of surface veins or stretch marks

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

- Thinning of the skin
- Appearance of surface veins or stretch marks
- Inflammation or swelling of the hair root
- Increased hair growth on parts of the body
- Red rash around the mouth (perioral dermatitis)
- Skin rash with inflammation or swelling (allergic contact dermatitis)
- Lightening of skin colour in the area you have used the cream
- An increase in pressure inside the eye (signs are eye pain, red eye, decreased or cloudy vision)
- Your adrenal glands may stop working properly. Signs are tiredness, depression and anxiety

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.

5. HOW TO STORE FUCIBET

- Keep out of the reach and sight of children.
- Do not use Fucibet after the expiry date stated on the carton or tube label after 'Exp'. The expiry date refers to the last day of that month.
- Do not store above 30°C.
- Discard 3 months after first opening.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Fucibet contains

- There are two active ingredients, fusidic acid and betamethasone valerate.

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

- The other ingredients are macrogol cetostearyl ether, cetostearyl alcohol, chlorocresol, liquid paraffin, sodium dihydrogen phosphate, white soft paraffin, all-rac- α -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.

It comes in tubes containing 30g.

Manufactured by: LEO Laboratories Limited, Dublin 12, Ireland.

Procured from within the EU and repackaged by the PPA holder: B&S Healthcare, Unit 4, Bradfield Road, Ruislip, Middlesex, HA4 0NU, UK.

Fucibet® 20mg/g + 1mg/g Cream
PPA No: 1328/183/1

POM

Leaflet date: 12.02.2013

Fucibet is a registered trademark of LEO Laboratories Limited.