APPROVED PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S4

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM:

Fucibet Cream

Fusidic acid anhydrous 20 mg and 1 mg betamethasone (as valerate) /1 g Cream

Read all of this leaflet carefully before you start using Fucibet Cream

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- **Fucibet Cream** has been prescribed for you personally and you should not share your **Fucibet Cream** with other people. It may harm them, even if their symptoms are the same as yours.

1. WHAT *FUCIBET CREAM* CONTAINS:

The active substances are: Each 1 g of cream contains 20 mg fusidic acid anhydrous and 1 mg betamethasone (as valerate). Preservative: Chlorocresol 0,1 % *m/v*

The other ingredients are: cetostearyl alcohol, liquid paraffin, macrogol cetostearyl ether, purified water, sodium dihydrogen phosphate dihydrate, white soft paraffin.

2. WHAT *FUCIBET CREAM* IS USED FOR:

Fucibet Cream 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 Cream works by:

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

Fucibet Cream is used for the short term (up to 2 weeks) treatment of:

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

3. BEFORE YOU USE *FUCIBET CREAM*

Do not use Fucibet Cream:

• If you are allergic (hypersensitive) to fusidic acid or betamethasone valerate.

• If you are allergic (hypersensitive) to any of the other ingredients in **Fucibet Cream**.

• 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 by tuberculosis or syphilis.

• 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.

• If you have reacted to vaccinations.

▪ In pregnant women and women who are breast-feeding their infants.

▪ In children under the age of 2 years.

Take special care with Fucibet Cream

• If you use the cream over a long time or in large amounts, the chance of getting any side effects increases. Also your skin may get more sensitive to **Fucibet Cream**.

▪ Long term treatment in children older than 2 years should particularly be avoided, as adrenal suppression can occur even without occlusion.

• Unless your doctor has told you to, you must not use **Fucibet Cream** on sensitive areas on the face such as the nostrils, ears, lips, or the genitals, or open wounds, thin skin, skin ulcers, broken veins or acne.

• Take special care if you are going to use **Fucibet Cream** near your eyes or the eyes of a child. If the cream gets into the eye, this may lead to glaucoma, a condition where the pressure inside the eye is increased.

▪ Do not use **Fucibet Cream** for more than 7 days if you do not see any signs of improvement.

Pregnancy and Breast-Feeding

Do not use **Fucibet Cream** if you are pregnant.

Safety in pregnancy and breast-feeding has not been established.

You should not use **Fucibet Cream** if you are breast-feeding your baby.

If you are pregnant or become pregnant or breast-feeding your baby while using Fucidin H Cream, please consult your doctor, pharmacist or other healthcare professional for advice.

Driving and using machinery:

Usually **Fucibet Cream** 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.

Taking other medicines with Fucibet Cream

Fucibet Cream is not known to have any interactions with 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.

If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of Fucibet Cream with these medicines may cause undesirable interactions. Please consult your doctor, pharmacist or other health care professional, for advice.

4. HOW TO USE *FUCIBET CREAM:*

Do not share the **Fucibet Cream** prescribed for you with any other person.

Always use **Fucibet Cream** exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Your doctor will tell you how long your treatment with **Fucibet Cream** will last.

If you have the impression that the effect of **Fucibet Cream** is too strong or too weak, tell your doctor or pharmacist.

How to put on Fucibet Cream

Fucibet Cream is only for using on your skin or the skin of a child older than 2 years of age. 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 Cream**. 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 Cream**.

If you accidentally get any **Fucibet Cream** 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 Cream to use

It is recommended that you do not cover 30 % of your skin area at any one application. Your doctor will tell you how much **Fucibet Cream** to use.

The usual treatment time is up to two weeks. Ask your doctor before using **Fucibet Cream** for any longer.

If there is no improvement after 7 days you should stop using the cream and go back to your doctor.

Usually, you should use **Fucibet Cream** two to three times each day. Use it in the morning, afternoon and evening. To remind you to use **Fucibet Cream** 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 **Fucibet Cream** so often.

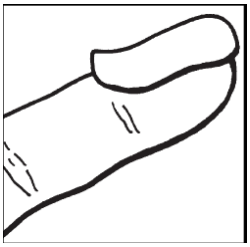
Adults and children:

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.

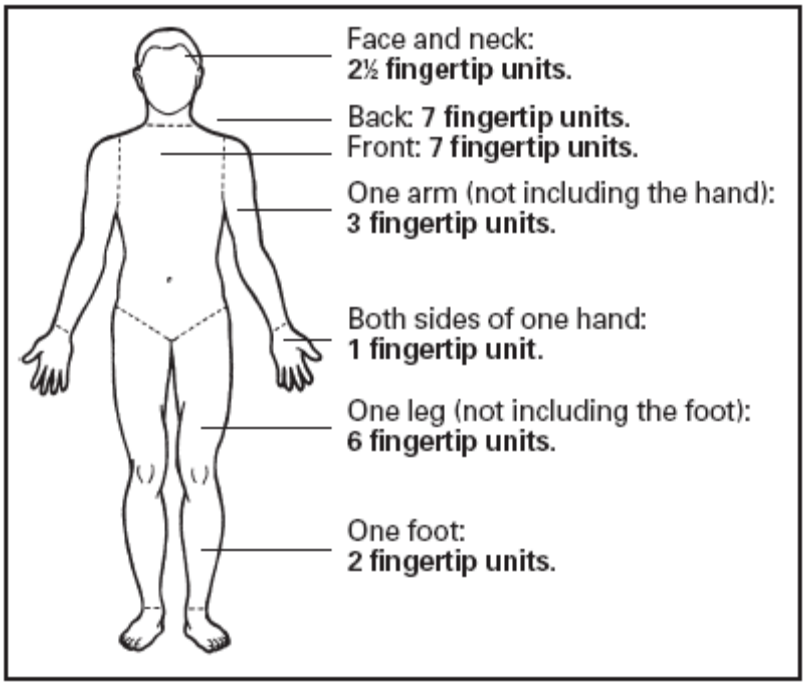
You can use your first (index) finger to measure how much **Fucibet Cream** to use.

Squeeze the cream along your finger from the tip to the first joint as shown in the diagram. This is called a fingertip unit.

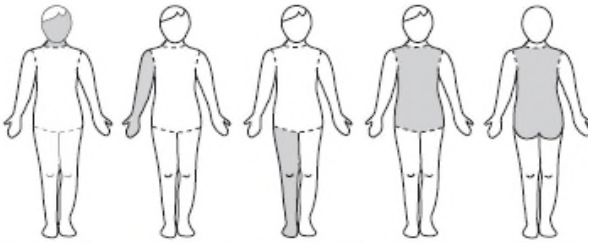
The usual number of finger tip units you need to cover different parts of the body is shown in the diagrams. If you need to use a little more or a little less do not worry. If you are using the cream on a child still use an adult finger to measure out the fingertip unit.



For an adult



For children under 12 years



Child's age	Number of fingertip units needed				
	Face and neck	Arm and hand	Leg and foot	Front	Back incl. 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 use more Fucibet Cream than you should:

Overdosage has not been known to occur

In the event of overdosage, consult your doctor or pharmacist. If neither is available, rush the patient to the nearest hospital or poison control centre.

If you forget to take Fucibet Cream:

If you forget to use **Fucibet Cream**, use it as soon as you remember. Then next use **Fucibet Cream** at the usual time. If you have any further questions about using **Fucibet Cream**, please ask your doctor or pharmacist.

5. POSSIBLE SIDE EFFECTS

Fucidin H Cream can have side effects.

Not all side effects reported for **Fucibet Cream** are included in this leaflet. Should your general health worsen while taking **Fucibet Cream**, please consult your doctor, pharmacist or other healthcare professional for advice.

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, if:

- 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 children older than 2 years of age. They are also more likely if the skin is covered with a dressing, bandage or nappy.

Skin problems

Less frequent side effects

- Skin irritation (including itching and a burning or stinging sensation)
- Worsening of your eczema.
- Skin inflammation in the area where the medicine is used (swollen hand)
- Skin dryness
- Inflammation of the skin on the head region

Other side effects reported, include:

- Flu like illness
- Sore throat
- Cold sores, fever blisters.
- Middle ear infection
- Urinary tract infection

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 following side effects occur:

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

Some of the ingredients of Fucibet Cream can also have side-effects, e.g.

- Cetostearyl alcohol. This may give you an itchy rash and inflammation on the skin where you apply the cream.
- Chlorocresol. This is a preservative. It may give you an allergic reaction.

Please ask your doctor if you are worried about any of the ingredients in **Fucibet Cream**.

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

6. STORING AND DISPOSING OF *FUCIBET CREAM:*

Store at or below 25 °C.

You may use **Fucibet Cream** for 3 months after the first opening, thereafter discard.

KEEP OUT OF REACH AND SIGHT OF CHILDREN.

Keep well closed.

Store in outer carton until use.

Do not use after the expiry date stated on the carton.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

7. IDENTIFICATION *OF FUCIBET CREAM*

A white to off-white homogenous cream.

8. PRESENTATION OF *FUCIBET CREAM*:

Fucibet Cream is packaged in aluminium tubes with membrane and a reclosable polyethylene screw cap. The aluminium tubes are lacquered inside with a coating on the entire surface and with a sealant lacquer in the fold area. The pack sizes are 5 g, 15 g, 30 g & 60 g.

9. REGISTRATION NUMBER/REFERENCE NUMBER:

45/13.4.1/0678

10. NAME AND ADDRESS OF REGISTARTION HOLDER:

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