FUCICORT® CREAM

Fusidic acid / Betamethasone (20mg/g / 1mg/g)

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What Fucicort® Cream is used for

Fucicort® Cream is used to treat conditions where the skin is inflamed (eczema or dermatitis) and also infected by germs (bacteria).

How Fucicort® Cream works

Fucicort® 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).

Fucicort® Cream works by the antibiotic killing germs that cause infections and corticosteroid help to reduce any swelling, redness or itchiness of your skin.

Your doctor may have prescribed this medication for another reason. Ask your doctor if you have any questions about why this medication has been prescribed for you.

Before you use Fucicort® Cream

- When you must not use it

- If you are allergic (hypersensitive) to Fusidic acid or betamethasone valerate
- If you are allergic (hypersensitive) to any of the other ingredients in this medicine.
- If you have perioral dermatitis. This is a red spotty rash around your mouth or chin

- If you have skin conditions caused by a virus such as cold sores or chickenpox
- If you have skin condition caused by fungus
- If you have a skin condition called acne rosacea. This is the redness and inflammation over your nose and cheeks. Ask your doctor if you are unsure.
- If you have skin conditions caused by tuberculosis (TB) or syphilis.
- If you have skin conditions such as boils or spots.

Pregnancy and lactation

Please ask your doctor or pharmacist for advice before using Fucicort® Cream:

- 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.

- <u>Before you start to use it</u>

- Tell your doctor if you have allergies to any other medicines, foods , preservatives or dyes
- Tell your doctor if you plan to become pregnant or breastfeeding.

- 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.

How to use Fucicort® Cream

- This medicine is only for using on your skin. 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 Fucicort® 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 Fucicort® Cream.

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 to use

Your doctor will tell you how much Fucicort® Cream to use.

<u>- When to use it</u>

Usually, you should use this medicine 2–3 times each day. 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. Follow the advice of your doctor.

- How long to use it

Continue taking Fucicort[®] Cream for as long as your doctor recommends.

- If you forget to use it

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 further questions about using this medicine, please ask your doctor or pharmacist.

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- <u>If you use too much (overdose)</u>

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are using it

- <u>Things you must do</u>

- Always use Fucicort[®] Cream exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.
- Please tell your doctor or pharmacist treating you that you are using Fucicort[®] Cream
- Please tell your doctor immediately if you become pregnant while using this medicine.

- Things you must not do

- Do not stop taking the medicine unless advised by your doctor
- Do not take any new medicines without consulting your doctor
- Do not give Fucicort[®] Cream to anyone else, even if they have the same symptoms or conditions as you.

- Things to be careful of

- 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 Fucicort[®] 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 Fucicort[®] Cream on thin skin, skin ulcers, broken veins or acne.

Side effects

Like all medicines, Fucicort[®] Cream 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:

- Dilatation of the superficial blood vessels
- Thinning of the skin
- Stretch marks
- Glaucoma or an increase in pressure inside the eye. Signs are eye pain, red eye, decreased or cloudy vision
- Eye cataracts. Signs are cloudy or foggy vision

- Adrenal glands may stop working properly. Signs are tiredness, depression and anxiety.
- Excessive production of adrenal cortical hormones.
 You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835490, or visiting the website npra.gov.my
 [Consumers → Reporting Side Effects to Medicines
 (ConSERF) or Vaccines
 (AEFI)]

Storage and Disposal of Fucicort[®] Cream

- <u>Storage</u>

- Keep out of the reach and the sight of children.
- Do not use *Fucicort* [®]Cream after the expiry date on the carton. The expiry date is the last day of that month.
- Do not keep 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 store above 30°C.

- <u>Disposal</u>

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.

Product Description <u>- What it looks like</u>

Fucicort® Cream is a white to offwhite cream. Fucicort® Creamcomes in tubes of 5g,15g

FUCICORT® CREAM

Fusidic acid / Betamethasone (20mg/g / 1mg/g)

- Ingredients

- Active ingredients
 - Fusidic acid 20mg/g
 - Betamethasone 1mg/g

- Inactive ingredients

- Cetostearyl alcohol
- Chlorocresol
- Sodium dihydrogen phosphate
- dihydrate
- Liquid paraffin
- White soft paraffin
- Sodium hydroxide
- Nitrogen
- all-rac-alpha tocopherol
- macrogol cetostearyl ether

Important information about some of the ingredients of Fucicort® Cream

Fucicort® Cream contains:

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

Please ask your doctor if you are worried about any of the ingredients in this medicine.

<u>- MAL number:</u> MAL19913375AZ

Manufacturer LEO Laboratories Ltd 285, Cashel Road, Crumlin, Dublin 12, Ireland

Product Registration Holder

DKSH Malaysia Sdn Bhd B-11-01, The Ascent, Paradigm No.1, Jalan SS 7/26A, Kelana Jaya Petaling Jaya Selangor.

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