Fusidic acid and betamethasone valerate

Cream containing 20mg fusidic acid and 1g betamethasone valerate.

What is in this leaflet

Please read this leaflet carefully before you start using Fucicort®.

This leaflet answers some common questions about Fucicort®. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you using Fucicort® against the benefits they expect it will have for you.

If you have any concerns about using this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

What Fucicort® is used for

Fucicort® 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.

Fucicort® works by:

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

Fucicort® is used to treat:

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

Your doctor may have prescribed Fucicort® for another reason.

Ask your doctor if you have any questions about why Fucicort® has been prescribed for you.
Before you use Fucicort®

When you must not use it

Do not use Fucicort® if:

- You are allergic (hypersensitive) to fusidic acid, betamethasone valerate or any of the other ingredients in your medicine (see Product Description at the end of this leaflet for a list of ingredients).
- You have a skin condition called acne rosacea. This is redness and inflammation over your nose and cheeks. Ask your doctor if you are unsure.
- You have a skin condition called perioral dermatitis. This is a red spotty rash around your mouth or chin.
- You have a skin condition caused only by bacteria, virus or fungus that is not being treated, or is not controlled by existing treatment. Using Fucicort® may make these conditions worse or hide their symptoms. Examples include boils or spots, cold sores, chickenpox and athlete’s foot. Ask your doctor if you are unsure.
- You have ulcers on the area to be treated.
- You have a skin condition caused by tuberculosis that is not being treated or is not controlled by existing treatment. Ask your doctor if you are unsure.

Fucicort® should not be applied to the face.

If you are not sure whether you should start using Fucicort®, talk to your doctor.

Before you start to use it

Tell your doctor if:

- You are pregnant or plan to become pregnant
- You are breastfeeding
- You have allergies to any other medicines or any other substances

Taking other medicines

Tell your doctor if you are taking any other medicines, including medicines that you buy without a prescription from your pharmacy, supermarket or health food shop. You should also tell any health professional who is prescribing a new medication for you that you are taking Fucicort®.
How to use Fucicort®

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 Fucicort®. Rub the medicine gently on the skin.

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

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

Adults and children:
Your doctor should tell you the dose that is right for you or your 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 Fucicort® to use. Squeeze the cream along your finger from the tip to the first joint. This is called a fingertip unit (as shown in diagram below).

The usual number of finger tip units you need to cover different parts of the body is described below. 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:

**Neck**: 2½ fingertip units.

**Back**: 7 fingertip units.

**Front**: 7 fingertip units.

**One arm (not including the hand)**:
3 fingertip units.

**Both sides of one hand**:
1 fingertip unit.

**One leg (not including the foot)**:
6 fingertip units.

**One foot**:
2 fingertip units.

For a child aged under 11 years:

<table>
<thead>
<tr>
<th>Child's age</th>
<th>Neck</th>
<th>Arm and hand</th>
<th>Leg and foot</th>
<th>Front</th>
<th>Back (including buttocks)</th>
</tr>
</thead>
<tbody>
<tr>
<td>3-6 months</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1½</td>
</tr>
<tr>
<td>1-2 years</td>
<td>1½</td>
<td>1½</td>
<td>2</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>3-5 years</td>
<td>1½</td>
<td>2</td>
<td>3</td>
<td>3</td>
<td>3½</td>
</tr>
<tr>
<td>6-10 years</td>
<td>2</td>
<td>2½</td>
<td>4½</td>
<td>3½</td>
<td>5</td>
</tr>
</tbody>
</table>
When to use it

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

How long to use it

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.

If you forget to take it

If it is almost time for your next dose, skip the dose you missed and apply your next dose when you are meant to. Otherwise, apply it as soon as you remember, and then go back to using it as you would normally.

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

This medicine has been prescribed for you. Do not pass it onto others. It may harm them, even if their symptoms are the same as yours.

While you are using Fucicort®

Things you must do

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

If you are about to be started on any new medicine tell your doctor and pharmacist that you are taking Fucicort®.

Tell your doctor if for any reason you have not used Fucicort® as prescribed. Otherwise your doctor may think that it was not effective and change your treatment unnecessarily.

Things you must not do

Do not give Fucicort® to anyone else, even if they have the same condition as you.
Things to be careful of

If you use the cream over a long time (ie. greater than 4 weeks), in large amounts or in skin folds, it may make the chance of getting any side effects higher. Also your skin may get more sensitive to this medicine.

Babies and children up to the age of four should not be treated for longer than 3 weeks. Side effects will be more likely if large amounts are used or the skin is covered with a dressing, bandage or nappy.

Fucicort® contains cetostearyl alcohol and chlorocresol. Cetostearyl alcohol may cause a skin reaction in some patients. Chlorocresol may cause an allergic reaction in some patients. Talk to your doctor if you require more information.

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.

In case of overdose

If you take too much (overdose)

Immediately telephone your doctor or the New Zealand National Poisons Centre (telephone 0800 POISON or 0800 764 766), or go to accident and emergency at your nearest hospital, if you think that you or anyone else may have taken too much Fucicort®.

Do this even if there are no signs of discomfort or poisoning. Urgent medical assistance may be required.

Side Effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using Fucicort®.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the adverse effects. Ask your doctor or pharmacist to answer any questions you may have.

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
- Worsening of your eczema
- Burning feeling
- Itching
- Dry skin
- Pain or irritation at the site of application

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

- Rash, such as hives
- Skin redness
- Swelling or small bumps at the site of application

Some side effects are known to be caused by the types of steroid in Fucicort®.
You should tell your doctor if any of the side effects occur:

- Thinning of the skin
- Stretch marks
- Appearance of blood vessels and redness on the skin surface
- Increased growth of your body hair
- Increased sweating
- Red spotty rash around the mouth or chin
- Lightening of your skin colour
- Bruising
- Glaucoma (increased eye pressure)
- Adrenal glands may stop working properly. Signs are tiredness, depression and anxiety.

Other adverse effects not listed above may also occur in some patients. Tell your
doctor if you notice any other effects.

Do not be alarmed by this list of possible adverse effects. You may not
experience any of them.
After using Fucicort®

Storage

- Fucicort® must be stored in a cool dry place where the temperature stays below 30 °C.
- Keep Fucicort® out of the reach and the sight of children. A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.
- Do not store Fucicort® in the bathroom, near a sink or in a car on hot days. Heat and dampness can destroy some medicines.
- Do not use Fucicort® after the expiry date on the carton.

Disposal

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

What it looks like

Fucicort® is a white to off white cream, available in tubes of 15 g.

Ingredients

Active ingredient(s):

Fusidic acid and betamethasone valerate.

Inactive ingredients:

Macrogol cetostearyl ether (Cetomacrogol 1000), cetostearyl alcohol, chlorocresol, liquid paraffin, monobasic sodium phosphate dihydrate, white soft paraffin, all-rac-α-tocopherol, and purified water.

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

Chlorocresol is a preservative. It may give you an allergic reaction. Please read the “Side Effects” section 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.
Sponsor Details

Fucicort® is supplied in New Zealand by:

LEO Pharma Ltd
Level 31, Vero Centre, 48 Shortland Street,
Auckland 1010, New Zealand
New Zealand Toll Free No: 0800 497 456

Date of Preparation

This leaflet was prepared in January 2016.

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