

PACKAGE LEAFLET

Package leaflet: Information for the patient

Eczibet 20 mg/g + 1 mg/g cream (fusidic acid / betamethasone)

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- 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 only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- In this leaflet Eczibet 20 mg/g + 1 mg/g cream will be called Eczibet.

What is in this leaflet:

1. What Eczibet is and what it is used for
2. What you need to know before you use Eczibet
3. How to use Eczibet
4. Possible side effects
5. How to store Eczibet
6. Contents of the pack and other information

1. What Eczibet is and what it is used for

Eczibet contains two different types of medicine. One medicine is called fusidic acid. It is a type of antibiotic.

The other medicine is called betamethasone. It is a type of corticosteroid (steroid). These two medicines work at the same time in different ways.

Eczibet works by:

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

Eczibet is used to treat:

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

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

2. What you need to know before you use Eczibet

Do not use Eczibet

- If you are allergic to fusidic acid or betamethasone or any of the other ingredients in this medicine (listed in Section 6).
- To treat infected dermatitis in infants under one year of age.
- To treat acne vulgaris.

- 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 skin conditions caused by tuberculosis (TB) or syphilis.
- 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 or more generalised infections caused by a fungus, e.g. candidiasis.

Warnings and precautions

Talk to your doctor or pharmacist, before using Eczibet:

- Do not use the cream on yourself or a child for more than 2 weeks; this is to avoid bacteria becoming resistant to the antibiotic and to avoid the steroid causing you side effects.
- 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 increased pressure in the eye which may cause loss of vision (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.
- Do not use the cream under bandages or dressings (as this increases the action of steroids).
- You must not use the medicine for a long time on your face.
- Unless your doctor has told you to, you must not use Eczibet 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 Eczibet on thin skin, skin ulcers or broken veins.
- Your adrenal glands may stop working properly. Signs are tiredness, depression and anxiety. This can be reversed by stopping Eczibet.

Contact your doctor if you experience blurred vision or other visual disturbances.

If there is a worsening of your condition during use consult your prescriber.

You may be experiencing an allergic reaction, have an infection or your condition requires a different treatment. If you experience a recurrence of your condition shortly after stopping treatment, within 2 weeks, do not restart using the cream without consulting your prescriber unless your prescriber has previously advised you to do so. If your condition has resolved and on recurrence the redness extends beyond the initial treatment area and you experience a burning sensation, please seek medical advice before restarting treatment.

Do not smoke or go near naked flames - risk of severe burns. Fabric (clothing, bedding, dressings, etc) that has been in contact with this product burns more easily and is a serious fire hazard. Washing clothing and bedding may reduce product build-up but not totally remove it.

Other medicines and Eczibet

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

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before using this medicine:

- If you are pregnant, or think you are pregnant: fusidic acid/betamethasone should not be used during pregnancy, unless you are told to do so by your doctor.
- If you are breast-feeding, fusidic acid/betamethasone may be used by women who are breast-feeding, but the cream should not be applied to the breasts to avoid accidental ingestion by the infant.

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.

Eczibet contains cetostearyl alcohol and chlorocresol:

- Cetostearyl alcohol. May cause local skin reactions (e.g. contact dermatitis).
- Chlorocresol. May cause allergic reactions.

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

3. How to use Eczibet

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

How to put on Eczibet

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 Eczibet. Apply thinly to the affected areas. 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 Eczibet.

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 Eczibet to use

Your doctor will tell you how much Eczibet 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.

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 Eczibet to use. Squeeze the cream along your finger from the tip to the first joint. This is called a fingertip unit.

The usual number of fingertip units you need to cover different parts of the body is described hereafter. 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:

Site of application	Usual number of fingertip units of cream
Face and neck	2½
Back of the trunk	7
Front of the trunk	7
One arm (not including the hand)	3
One hand (both sides)	1
One leg (not including the foot)-	6
One foot	2

FOR A CHILD FROM 1 TO 10 YEARS:

Site of application	Usual number of fingertip units of cream		
	For a child aged 1-2 years	For a child aged 3-5 years	For a child aged 6-10 years
Face and neck	1½	1½	2
One arm and hand	1½	2	2½
One leg and foot	2	3	4½
Front of the trunk	2	3	3½
Back of the trunk including the buttocks	3	3½	5

If you use more Eczibet than you should

Tell your doctor straight away if you have used more Eczibet than you should. You may need to stop using this medicine.

If you forget to use Eczibet

If you forget to use this medicine, use it as soon as you remember. Then next use this medicine at the usual time. Do not use a double dose to make up for the forgotten dose.

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

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, eyelids, lips, tongue or throat swell
- Your skin develops a severe rash.

Other possible side effects:

- Steroid withdrawal reaction: If used continuously for prolonged periods a withdrawal reaction may occur on stopping treatment with some or all of the following features: redness of the skin which can extend beyond the initial area treated, a burning or stinging sensation, intense itching, peeling of the skin, oozing open sores.
- 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.

Uncommon (may affect up to 1 in 100 people):

- Itchy rash and skin inflammation in the area where the medicine is used
- Burning feeling
- Itching
- Worsening of your eczema
- Dry skin
- Application site pain
- Application site irritation

Rare (may affect up to 1 in 1,000 people):

- Hives
- Skin redness
- Skin rash
- Application site swelling
- Application site blisters

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

- Thinning of the skin
- Stretch marks
- Small veins near the surface of the skin become visible
- Changes in growth of your body hair
- Excessive sweating
- Red spotty rash around the mouth or chin
- Lightening of your skin colour
- Redness of the skin, nose or mouth
- Loss of vision caused by damage to the optic nerve in the eye, caused by increased pressure in the eye (glaucoma) or by clouding of the lens in the eye (cataract)
- Adrenal glands may stop working properly. Signs are feeling sick, stomach pain, headache, poor weight gain, lacking energy, tiredness, depression and anxiety.

Not known (frequency cannot be estimated from the available data)

- Blurred vision

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, website: www.hpra.ie. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Eczibet

- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date which is stated on the carton and tube after EXP. The expiry date is the last day of that month.
- Do not keep the tube for more than 6 months after you first open it. Make a note of the date you first opened the tube in the space provided on the carton, next to “Open date:”.
- Do not store the medicine above 30°C.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Eczibet contains

- The active substances are, fusidic acid and betamethasone. Each gram of cream contains 20 mg fusidic acid and 1 mg betamethasone (as betamethasone valerate).
- The other ingredients are macrogol cetostearyl ether, cetostearyl alcohol, chlorocresol (see section 2 ‘Eczibet contains cetostearyl alcohol and chlorocresol’), liquid paraffin, sodium dihydrogen phosphate dihydrate, white soft paraffin, all-rac- α -tocopherol, purified water and sodium hydroxide.

What Eczibet looks like and contents of the pack

Eczibet is a white to off-white smooth cream in an aluminium tube, with a white conical polyethylene screw cap.

Eczibet comes in tubes of 5g; 15g; 30g and 60g.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

McDermott Laboratories Ltd. T/A Gerard Laboratories,
35/36 Baldoyle Industrial Estate,
Grange Road,
Dublin 13,
Ireland

Manufacturer

McDermott Laboratories Ltd. T/A Gerard Laboratories, 35/36 Baldoyle Industrial Estate, Grange Road, Dublin 13, Ireland.
Mylan Hungary Kft., Mylan utca 1, Komárom 2900, Hungary.

This medicinal product is authorized in Member States of the EEA under the following names:

Denmark: Fusidinsyre / Betamethasonevalerat Mylan 20 mg/g + 1 mg/g Creme
Germany: Fusidinsäure/ Betamethason Mylan 20 mg/g + 1 mg/g Creme
Greece: Fusidic acid/ Betamethasone valerate / Mylan 20 mg/g + 1 mg/g Cream
Ireland: Eczibet 20 mg/g + 1 mg/g cream
Italy: FUSAPIELBETA
Portugal: Betametasona + Ácido fusídico Mylan 1 mg/g + 20 mg/g Creme
United Kingdom: Xemacort 20 mg/g + 1 mg/g cream

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