

Package leaflet: Information for the patient
Fusidic acid/ Betamethasone 20 mg/g + 1 mg/g cream

(fusidic acid and 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 Fusidic acid/Betamethasone 20 mg/g + 1 mg/g cream will be called Fusidic acid/Betamethasone.

What is in this leaflet:

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

1. What Fusidic acid/Betamethasone valerate is and what it is used for

Fusidic acid/Betamethasone 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.

Fusidic acid/Betamethasone works by:

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

Fusidic acid/Betamethasone 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 Fusidic acid/Betamethasone

Do not use Fusidic acid/Betamethasone

- 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 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.

Warnings and precautions

Talk to your doctor or pharmacist, before using Fusidic acid/Betamethasone

- 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.
- You must not use the medicine for a long time on your face.
- Unless your doctor has told you to, you must not use Fusidic acid/Betamethasone 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 Fusidic acid/Betamethasone on thin skin, skin ulcers, broken veins or acne.

Other medicines and Fusidic acid/Betamethasone

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 taking this medicine.

- If you are pregnant, or think you are pregnant. You must not use your medicine for a long time or in large amounts.
- If you are breast-feeding, Fusidic acid/Betamethasone should not be used on the breast.

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.

Fusidic acid/Betamethasone 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 Fusidic acid/Betamethasone

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 Fusidic acid/Betamethasone

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 Fusidic acid/Betamethasone. 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 Fusidic acid/Betamethasone.

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 Fusidic acid/Betamethasone to use

Your doctor will tell you how much Fusidic acid/Betamethasone 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.

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.

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 Fusidic acid/Betamethasone 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 finger tip 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 finger tip 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 forget to use Fusidic acid/Betamethasone

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:

- 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 probably affect up to 1 in 100 people):

- Skin irritation
- Burning feeling

- Itching
- Worsening of your eczema
- Stinging feeling
- Skin redness

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

- Hives
- Dry skin

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

- Itchy rash and skin inflammation in the area where the medicine is used.
- Rash
- Small veins near the surface of the skin become visible.

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

- Thinning of the skin
- Stretch marks
- Inflammation or swelling of the hair root (folliculitis)
- Changes in growth of your body hair
- Red spotty rash around the mouth or chin
- Lightening of your skin colour
- Loss of vision caused by a damage to the optic nerve in the eye, caused by an increased pressure in the eye (glaucoma)
- Adrenal glands may stop working properly. Signs are feeling sick, stomach pain, headache, poor weight gain, lacking energy, tiredness, depression and anxiety.

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 the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Fusidic acid/Betamethasone

- 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 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.
- 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 Fusidic acid/Betamethasone contains

- The active substances are fusidic acid and betamethasone..
- Fusidic acid/Betamethasone contains 20 mg/g of fusidic acid and 1 mg/g of betamethasone.
- The other ingredients are macrogol cetostearyl ether, cetostearyl alcohol, chlorocresol (see section 2 'Fusidic acid/Betamethasone contains cetostearyl alcohol and chlorocresol'); liquid paraffin, sodium dihydrogen phosphate dihydrate, white soft paraffin, all-rac- α -tocopherol, purified water and sodium hydroxide.

What Fusidic acid/Betamethasone looks like and contents of the pack

Fusidic acid/Betamethasone is a white to off-white smooth cream in an aluminium tube. Fusidic acid/Betamethasone comes in tubes of 5g; 15g; 30g and 60g.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Goapharma, 6 rue Solférino, 78000 Versailles, France.

Manufacturer

KYMOS Pharma Services, S.L., Ronda de Can Fatjo, 7B (Parque Tecnológico del Vallès), Cerdanyola del Vallès, 08290 Barcelona, Spain.

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

Latvia: ENOSAT 20 mg/1 mg/g krēms

Lithuania: ENOSAT 20 mg/1 mg/g kremas

Poland: Dermisil

This leaflet was last revised in

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