

Package leaflet: Information for the user

Fusidic acid / Betamethasone Bailleul 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.

What is in this leaflet

1. What Fusidic acid / Betamethasone Bailleul 20 mg/g + 1 mg/g cream is and what it is used for
2. What you need to know before you use Fusidic acid / Betamethasone Bailleul 20 mg/g + 1 mg/g cream
3. How to use Fusidic acid / Betamethasone Bailleul 20 mg/g + 1 mg/g cream
4. Possible side effects
5. How to store Fusidic acid / Betamethasone Bailleul 20 mg/g + 1 mg/g cream
6. Contents of the pack and other information

1. What Fusidic acid / Betamethasone Bailleul 20 mg/g + 1 mg/g cream is and what it is used for

Fusidic acid / Betamethasone Bailleul 20 mg/g + 1 mg/g 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). The two medicines work at the same time in different ways.

Fusidic acid / Betamethasone Bailleul 20 mg/g + 1 mg/g cream works by:

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

Fusidic acid / Betamethasone Bailleul 20 mg/g + 1 mg/g cream is used to treat:

- Conditions where the skin is inflamed (eczema or dermatitis) and infected, or might become infected, by germs (bacteria) in adults and children over 1 year.

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 Bailleul 20 mg/g + 1 mg/g cream

Do not use Fusidic acid / Betamethasone Bailleul 20 mg/g + 1 mg/g cream

- To treat infants under one year of age.
- If you are allergic to fusidic acid or betamethasone or any of the other ingredients of this medicine (listed in section 6).
- To treat infections caused by a fungus, such as athlete's foot or ringworm.
- To treat a skin condition caused by a virus, such as cold sores or chicken pox.
- 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 acne vulgaris.
- To treat a condition called perioral dermatitis. This is a red spotty rash around your mouth or chin.
- To treat a skin condition called rosacea. This is redness and inflammation over your nose and cheeks.

Ask your doctor if you are unsure.

Warnings and precautions

Talk to your doctor or pharmacist before using Fusidic acid / Betamethasone Bailleul 20 mg/g + 1 mg/g cream.

- Do not use for a long time, continuously (without stopping), as this medicine contains a steroid. 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).
- Contact your doctor if you experience blurred vision or other visual disturbances.
- Your adrenal glands may stop working properly. Signs are tiredness, depression and anxiety. This can be reversed by stopping Fusidic acid / Betamethasone Bailleul 20 mg/g + 1 mg/g cream.
- Do not use a large amount of the cream (follow your doctor's instructions).
- Use with caution on large skin areas, on the face and in skin folds.
- Do not use the cream on thinning skin, skin ulcers, acne (spots) or in skin folds (e.g. under breasts, groin area or armpits), vulnerable skin veins and perianal and genital pruritus. Unless your doctor has told you to, you must not use the cream on open wounds or sensitive areas such as the nostrils, ears, lips or genitals.
- If your condition worsens during use, stop treatment immediately and consult a pharmacist or doctor. You may be experiencing an allergic reaction (signs could include rash, itching and/or swelling of the mouth, tongue, face and throat), have an infection or your condition requires a different treatment.
- If you experience a recurrence of your condition shortly after stopping treatment, do not restart using the cream/ointment without consulting a pharmacist or doctor. If your condition has resolved but on recurrence the redness extends beyond the initial treatment area and you experience a burning sensation, please seek medical advice before restarting treatment.
- Corticosteroids can delay cicatrization i.e. skin healing.
- Do not use the cream under bandages or dressings (as this increases the action of steroids).
- Take special care if you are going to use this medicine on a child, as children are more sensitive to steroids.
- Take care if you have been or are susceptible to infections.
- 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.

Children

Do not give this medicine to children under one year of age.

Other medicines and Fusidic acid / Betamethasone Bailleul 20 mg/g + 1 mg/g cream

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.

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 might be pregnant; Fusidic acid / Betamethasone Bailleul 20 mg/g + 1 mg/g cream should not be used during pregnancy unless you are told to do so by your doctor.
- If you are breast-feeding; Fusidic acid / Betamethasone Bailleul 20 mg/g + 1 mg/g cream may be used by women who are breast-feeding, but the cream should not be applied to the breast.

Driving and using machines

This medicine should not have any effect on your ability to drive or use machinery. Check with your doctor if you feel any side effect that may stop you from driving or using machinery.

Fusidic acid / Betamethasone Bailleul 20 mg/g + 1 mg/g cream 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 or pharmacist if you are worried about any of the ingredients in this medicine.

3. How to use Fusidic acid / Betamethasone Bailleul 20 mg/g + 1 mg/g cream

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

How to put on Fusidic acid / Betamethasone Bailleul 20 mg/g + 1 mg/g cream

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.

Always wash your hands before using Fusidic acid / Betamethasone Bailleul 20 mg/g + 1 mg/g cream.

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 in the tube.

Apply thinly to the affected areas. If your doctor has told you to use it on your face be very careful to avoid your eyes. 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.

Unless you are using the cream to treat your hands, always wash your hands after using Fusidic acid / Betamethasone Bailleul 20 mg/g + 1 mg/g cream.

How much Fusidic acid / Betamethasone Bailleul 20 mg/g + 1 mg/g cream to use

Your doctor will tell you how much Fusidic acid / Betamethasone Bailleul 20 mg/g + 1 mg/g cream 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 seven days, you should stop using the cream and go back to your doctor.

Usually, you should use this cream 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.

Avoid using this medicine under occlusion (dressing, bandage or nappy on a baby). Follow the advice of your doctor.

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 index finger (first finger) to measure how much cream to use. Squeeze the cream from the tube along your index finger from the tip to the first joint. This amount of cream is one fingertip unit. The tables below show how much cream you need to cover different areas of your body. If you find you need slightly more or less cream than indicated, do not worry as this is only a general guide. If you are using the cream on a child, still use an adult finger to measure out the fingertip unit.

For adults

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 forget to use Fusidic acid / Betamethasone Bailleul 20 mg/g + 1 mg/g cream

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 a forgotten dose.

If you have any further questions on the use of 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. The most common side effect is itching.

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 lips and mouth start to tingle or swell**
- **Your face or throat swell**
- **Your skin develops a severe rash.**

Other possible side effects:

Other possible side effects which are less serious can also occur. You should tell your doctor about these as soon as possible.

Uncommon (may affect up to 1 in 100 people)

- Itchy rash and skin inflammation in the area where the medicine is used (contact dermatitis)
- Worsening of your eczema
- Skin burning feeling
- Itchy skin
- Dry skin
- Pain or skin irritation in the area where the medicine is used.

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

- Redness of the skin
- Hives
- Rash
- Swelling in the area where the medicine is used
- Redness of the skin due to widening of the small blood vessels.

Frequency not known (cannot be estimated from the available data)

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

The following additional side-effects are known to be caused by steroids and are more likely to occur after longer term use:

- Your adrenal glands may stop working properly. Signs are tiredness, depression and anxiety
- An increase in pressure inside the eye (signs are eye pain, red eye, decreased or cloudy vision) or eye cataracts (signs are cloudy or foggy vision)
- Thinning of the skin
- Skin rash with inflammation or swelling (contact dermatitis) or with pimples like acne
- Red rash around the mouth (perioral dermatitis)
- Appearance of surface veins or stretch marks
- Redness and inflammation over your nose and cheeks (rosacea)
- Redness
- Increased hair growth on the body
- Excessive sweating
- Lightening of skin colour
- Red blood spots under your skin.

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 Fusidic acid / Betamethasone Bailleul 20 mg/g + 1 mg/g cream

- 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 tube and carton after EXP. The expiry date refers to the last day of that month.
- Store below 30°C.
- Discard any remaining cream 6 months after first opening. Write the date you first opened the tube in the space provided on the carton.

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 Bailleul 20 mg/g + 1 mg/g cream contains

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

You can find important information about some of the ingredients in your medicine near the end of section 2 of this leaflet.

What Fusidic acid / Betamethasone Bailleul 20 mg/g + 1 mg/g cream looks like and contents of the pack

Fusidic acid / Betamethasone Bailleul 20 mg/g + 1 mg/g cream is a white to off-white, smooth, homogeneous cream in an aluminium tube, with a white conical polyethylene screw cap.

Fusidic acid / Betamethasone Bailleul 20 mg/g + 1 mg/g cream comes in tubes of 5 g, 15 g, 30 g and 60 g.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Laboratoires Bailleul S.A
14-16 Avenue Pasteur
L-2310 Luxembourg
Luxembourg

Manufacturer

KYMOS S.L
RONDA DE CAN FATJO, 7B (PARQUE TECNOLÓGICO DES VALLES)
CERDANYOLA DEL VALLES
08290 BARCELONE
ESPAGNE

This medicine is authorised in the Member States of the European Economic Area under the following names:

BE	Defucort 20 mg/g +1 mg/g crème
CZ	Imaxema 20 mg/g + 1 mg/g krém
ES	Cortifusin 20 mg/g + 1 mg/g crema
HU	Imaxema 20 mg/g + 1 mg/g krém
IT	Imafusin 20 mg/g + 1 mg/g crema
IE	Fusidic acid/Betamethasone Bailleul 20 mg/g + 1 mg/g cream
LU	Defucort 20 mg/g + 1 mg/g crème
MT	Cortofusin 20 mg/g + 1 mg/g Cream
RO	Imaxema 20mg/1mg/g, cremă
SK	Imaxema 20 mg/g + 1 mg/g, krém

This leaflet was last revised in

[To be completed nationally]