

Package leaflet: Information for the user

Betamethasone Valerate

0.1%w/w Cream

betamethasone valerate

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

1. What Betamethasone cream is and what it is used for

Betamethasone Valerate 0.1%w/w Cream (hereinafter referred to as Betamethasone cream) contains a topical steroid. 'Topical' means that it is put on the skin. Topical steroids are used on certain types of inflamed skin, to reduce the redness and itchiness. Betamethasone cream is used to treat inflamed skin conditions, such as eczema, in patients unresponsive to less potent creams or ointments. These steroids should not be confused with "anabolic" steroids misused by some body builders and athletes and taken as tablets or injections.

Corticosteroid creams, ointments and other topical preparations come in four different potencies or strengths. These are known as mild, moderately potent, potent or very potent. Healthcare professionals will usually refer to topical corticosteroid potency rather than strength. A potent or strong corticosteroid has a much stronger effect than a mild corticosteroid when using the same amount. The percentage of active ingredient that is sometimes included on product packaging does not indicate potency. Betamethasone valerate is classed as a strong corticosteroid. Your healthcare professional will prescribe or advise a steroid of the appropriate potency for your condition.

2. What you need to know before you use Betamethasone cream

Do not use Betamethasone cream:

- if you are allergic (hypersensitive) to betamethasone valerate or any of the other ingredients of Betamethasone cream (listed in section 6)
- on infants under one year of age
- on areas of skin which have the following conditions:
 - acne
 - rosacea (redness and spots or blisters in the centre of the face around the nose)
 - peri-oral dermatitis (spotty red rash around the mouth)
 - skin infections caused by viruses, bacteria or fungi, such as cold sores, herpes, chickenpox, impetigo, ringworm, athlete's foot, thrush
 - on areas of itchiness where the skin is not inflamed
 - on areas of skin other than those that you showed to your doctor
 - around the anus (back passage) or on the genitals (private parts) unless your doctor has told you to do so.

Do not use if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before using Betamethasone cream.

Warnings and precautions

Talk to your doctor or pharmacist before using Betamethasone cream:

- if you have had an allergic reaction, such as redness or itching, after applying any creams or ointments. Please tell your doctor or pharmacist if you have experienced allergies to creams or ointments in the past
- if you are using it around a leg ulcer you have had for a long time. You may be at increased risk of an allergic reaction or infection around the ulcer
- you **should not** normally use this cream on your face or on a child, where the skin thins easily unless your doctor has told you to do so. If possible, any course of treatment involving the face or a child should not last more than 5 days

- **do not** get the cream in your eyes. If you accidentally get some cream in your eyes wash it out and contact your doctor **immediately**
- if your doctor has prescribed the cream for psoriasis, you should let your doctor review your progress at regular intervals, as such treatment needs careful supervision
- if you are applying the cream under an airtight dressing, including a child's nappy. These dressings make it easier for the active ingredient to pass through the skin. It is possible to accidentally end up using too much
- if you are applying to a large surface area
- if you are applying the cream on broken skin or within the skin folds
- if you are applying near eyes or on eyelids, as cataracts or glaucoma may result if the cream repeatedly enters the eye
- if you have an infection of the skin as this will need to be treated
- if you are applying to thin skin such as the face or on children as their skin is thinner than adults and as a result may absorb larger amounts
- dressing or bandages should not be used on children or on the face where the cream is applied.

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 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.

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before using this medicine.

Other medicines and Betamethasone cream

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicine, especially if you are taking ritonavir and itraconazole medications.

Pregnancy and breast-feeding and fertility

If you are pregnant or are 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.

Driving and using machines

There are no known effects of this medicine on your ability to drive or use machinery.

Betamethasone cream contains propylene glycol, cetostearyl alcohol and chlorocresol

This cream contains propylene glycol, which can cause allergic reactions in some people, cetostearyl alcohol which may cause local skin reactions (e.g. contact dermatitis) and chlorocresol which may cause allergic reactions. If you have been told by your doctor that you are allergic to these ingredients contact your doctor before using this medicine.

3. How to use Betamethasone cream

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

Adults and children (over 1 year of age)

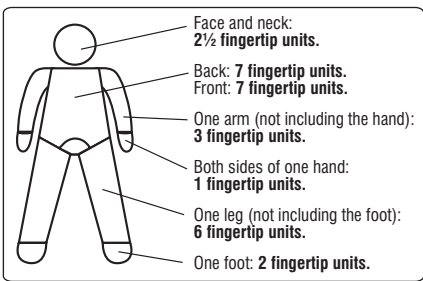
Wash your hands each time before you use the cream. Apply the cream in a **thin layer** to the area to be treated, and rub in gently.

You can measure how much cream to use with your fingertip. For children you will need to use less cream but still use an adult finger to measure out the fingertip unit. This picture shows one fingertip unit.



Wash your hands again when you have finished, unless you are treating the hands.

For an adult



Do not worry if you find you need a little more or less than this. It is only a rough guide.

For a child aged 1 - 10

Number of fingertip units needed					
Child's age	Face and neck	Arm and hand	Leg and foot	Front	Back including buttocks
1-2 years	1½	1½	2	2	3
3-5 years	1½	2	3	3	3½
6-10 years	2	2½	4½	3½	5

Most patients use the cream once or twice daily when they start treatment, but can use it less often as the condition improves.

This cream is for use on your skin only.

Do not use more than the amount prescribed for you. If anyone else helps to apply the cream, they should wear disposable plastic gloves or wash their hands thoroughly before and after using the cream.

You should not use the cream on large areas of the body for many weeks or months. This is particularly important when the cream is used to treat children. When used to treat children, the cream should not be used for a period longer than five days.

You should not normally use the cream on the face where the skin thins easily.

The germs that cause infections like warm, moist conditions under bandages or dressings so always clean the skin before a fresh dressing is put on.

If using on children **do not** cover the area treated with a nappy or dressing which does not let the skin breathe (occlusive dressing) unless your doctor has told you to do so. Covering the cream with an airtight dressing can make it easier for the active ingredient to pass through the skin. It is especially important in children not to exceed the prescribed amount.

A course of treatment for a child should not normally last more than 5 days - unless your doctor has told you to use it for longer.

Do not use Betamethasone cream on infants under one year of age

If the skin problem does not improve in 2 to 4 weeks, tell your doctor.

If you have psoriasis

If you have thick patches of psoriasis on your elbows or knees, your doctor may suggest applying the cream under an airtight dressing. It will only be at night to help the cream to start working. After a short period of time you will then apply the cream as normal.

If you apply Betamethasone cream to your face

You should only apply the cream to your face if your doctor tells you to. It should not be used for more than 5 days, as the skin on your face thins easily. **Do not let the cream get into your eyes.**

If you use more Betamethasone cream than you should

If you use more than you should, by mistake, on a few occasions, do not worry. If you apply a lot or a lot is accidentally swallowed, it could make you ill. Talk to your doctor or go to the hospital as soon as possible.

If you forget to use Betamethasone cream

If you forget to apply the cream at the usual time, apply it when you remember, unless it is close to the time for the next application. Do not apply a double amount to make up for a forgotten application.

If you stop using Betamethasone cream

It is important that you do not stop using your cream unless advised to do so by your doctor.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. If you notice any of the following reactions **stop using the cream** and speak to your doctor **immediately**:

- if you find that your skin condition gets worse, you develop a generalised rash or your skin becomes swollen during treatment. You may be allergic to Betamethasone cream, have an infection or need other treatment
- if you have psoriasis and get raised bumps with pus under the skin. This can happen very rarely during or after treatment and is known as pustular psoriasis.

Other side effects you may notice when using Betamethasone cream include:

Common: may affect up to 1 in 10 people

- a feeling of burning, pain, irritation or itching where the cream is applied.

Very rare: may affect up to 1 in 10,000 people

- an increased risk of infection
- an allergic skin reaction where the cream is applied
- rash, itchy bumpy skin or redness of the skin
- thinning and dryness of your skin and it may also damage or wrinkle more easily
- stretch marks may develop
- blood vessels under the surface of your skin may become more noticeable
- an increase or reduction in hair growth or hair loss and changes in skin colour
- weight gain, rounding of the face
- delayed weight gain or slowing of growth in children
- bones can become thin, weak and break easily
- cloudy lens in the eye (cataract) or increased pressure in eye (glaucoma)
- a decrease in the level of the hormone cortisol in your blood
- increased blood sugar levels or sugar in the urine
- high blood pressure

Not Known: frequency cannot be estimated from the available data

- blurred vision
- Steroid withdrawal reaction: If used over prolonged periods a withdrawal reaction, which might appear to be different from the previous condition, may occur in some patients during treatment or within days to weeks after 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.

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 or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Betamethasone cream

Keep out of the sight and reach of children. Do not store above 25°C, and protect from light in the original tube with the top screwed on. Do not use the cream after the expiry date, which is printed on the tube and carton. Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Contents of the pack and other information

What Betamethasone cream contains

This medicine contains the active ingredient betamethasone (as valerate) 0.1%w/w. It also contains a preservative, chlorocresol, as well as liquid paraffin, cetostearyl alcohol, cetomacrogol 1000, propylene glycol, sodium phosphate, citric acid and purified water.

What Betamethasone cream looks like and contents of the pack

The cream is available in tubes of 15g, 30g and 100g. Not all pack sizes may be marketed.

Marketing Authorisation Holder

Manx Healthcare Ltd, Unit 2, Bosworth Avenue, Tournament Fields, Warwick, CV34 6UQ, UK

Manufacturer

Beltapharm S.r.l. Via Stelvio 66, 20095 Cusano, Milan, Italy.

Other formats

To request a copy of this leaflet in Braille, large print or audio please call 01926 482511.

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