

PATIENT INFORMATION 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.

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects get serious, or if you notice any side effect not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet

1. What Betamethasone cream is and what it is used for
2. Before you use Betamethasone cream
3. How to use Betamethasone cream
4. Possible side effects
5. How to store Betamethasone cream
6. Further 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.

2. 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 (see section 6 for other ingredients).
- in 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.

Take special care with 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 where the skin thins easily unless your doctor has told you to do so. If possible, any course of treatment involving the face 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.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

There are no known interactions with other medications.

Pregnancy and breast-feeding

Ask your doctor or pharmacist for advice before taking any medication. It is advisable to avoid the extensive use of betamethasone in pregnancy. If you are pregnant or think you may be pregnant please tell your doctor or pharmacist before using this medication.

Driving and using machines

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

Important information about some of the ingredients of Betamethasone cream.

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 Betamethasone cream exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure. The usual dose is:

Adults and children (over 1 year of age)

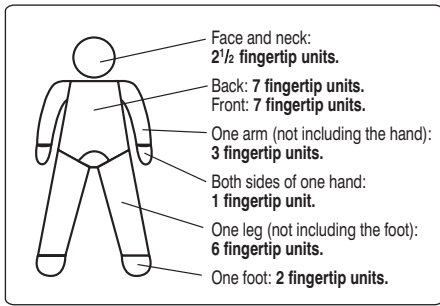
Wash your hands each time before you use the cream. Apply the cream in **a thin layer** to the area to be treated, and rub in gently.

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



(continued overleaf)

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.

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.

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.

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 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, Betamethasone cream 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**:

Very rare (occurs in less than 1 in 10,000 people)

- skin rash, itching, shortness of breath, wheezing and/or swollen face (symptoms of an allergic hypersensitivity reaction).

If you use large amounts of the cream, use it for a long time, or use it under an airtight dressing or baby's nappy you may notice the following side effects:

- your face shape seems to be changing ('moon' face) and/or you gain extra body weight unexpectedly (features of Cushing's syndrome)
- thinning of skin so that it damages more easily
- unusual purple stretch marks anywhere on your body
- surface veins may become more noticeable.

Other possible side effects:

Common (occurs in less than 1 in 10 people)

- burning and/or itching where the cream is applied.

Rare (occurs in less than 1 in every 1,000 people)

- glaucoma (high pressure in your eye) when used around your eyes
- if being treated for psoriasis (or when treatment is stopped), the condition gets worse.

(Frequency unknown)

- inflammation of the skin, including the mouth
- acne
- abnormal changes in hair growth or skin colour
- increased risk of skin infection.

In children, absorption of the active ingredient through the skin can affect the rate at which they grow.

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 Betamethasone cream

Keep the cream in a safe place, 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 packet.

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. Further 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., Taylor Group House, Warwick, CV34 5YA, United Kingdom.

Manufacturer

Beltapharm SpA, 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.

This leaflet was revised in February 2014

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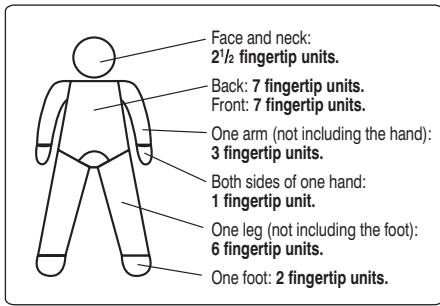
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