

PACKAGE LEAFLET: INFORMATION FOR THE USER

BELODERM

cream

BETAMETHASONE VALERATE

• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • Read all of this leaflet carefully before you start taking 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 •

What is in this leaflet?

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- 2 What you need to know before you use Beloderm
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1 WHAT BELODERM IS AND WHAT IT IS USED FOR

Beloderm contains a medicine called betamethasone valerate. It belongs to a group of medicines called steroids that reduce swelling and irritation. Beloderm is used to help reduce the redness and itchiness of certain skin problems, such as eczema, psoriasis and dermatitis.

2 WHAT YOU NEED TO KNOW BEFORE YOU USE BELODERM

Do not use Beloderm:

- if you are allergic (hypersensitive) to betamethasone valerate or any of the other ingredients of Beloderm
- on a child under 1 year
- to treat any of the following skin problems, it could make them worse:
 - acne
 - severe flushing of skin on and around your nose (rosacea)
 - spotty red rash around your mouth (perioral dermatitis)
 - itching around your back passage or private parts
 - infected skin (unless the infection is being treated with an anti-infective medicine at the same time)
 - itchy skin which is not inflamed

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

Warnings and precautions

Talk to your doctor or pharmacist before using Beloderm if:

- you have previously had an allergic reaction with another steroid
- 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.
- you have psoriasis, your doctor will want to see you more often.
- using for a chronic leg ulcer as you may be at increased risk of local allergic reaction or infection.
- you are applying to a large surface area
- you are applying the cream on broken skin or within the skin folds.
- you are applying near eyes or on eyelids, as cataracts or glaucoma may result if the cream repeatedly enters the eye.
- 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.
- Use on children or on the face should be limited to 5 days.

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 Beloderm

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.

Beloderm Cream contains chlorocresol and cetostearyl alcohol

Beloderm cream contains chlorocresol which may cause allergic reactions and cetostearyl alcohol which may cause local skin reactions (e.g. contact dermatitis).

3 HOW TO USE BELODERM

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

Using this medicine

- You usually apply Beloderm once or twice a day.

This may be reduced as your skin begins to get better.

- This cream is for use on your skin only.
- Do not use more than the amount prescribed for you.
- Do not use on large areas of the body for a long time (such as every day for many weeks or months) - unless your doctor tells you to.
- 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 you are applying the cream on someone else make sure you wash your hands after use or wear disposable plastic gloves.
- If your skin problem does not improve in 2 to 4 weeks, talk to your doctor.

Guidance on how to apply the cream

1 Wash your hands.

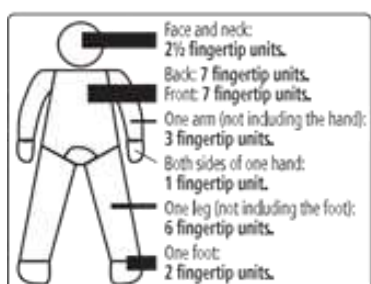
2 Apply a thin layer to the affected area(s) and gently rub into the skin until it has all disappeared.

You can measure how much Beloderm 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.



3 Unless you are meant to apply the cream to your hands as a part of the treatment, wash them again after using the cream.

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	1 ½	1 ½	2	2	3
3-5 years	1 ½	2	3	3	3 ½
6-10 years	2	2 ½	4 ½	3 ½	5

- Do not use it on children under 1 year of age
- 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.

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 Beloderm 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 Beloderm than you should

If you apply too much or if 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 Beloderm

If you forget to apply your cream, apply it as soon as you remember. If it is close to the time you are next meant to apply it, wait until this time.

If you stop using Beloderm

If you use Beloderm regularly make sure you talk to your doctor before you stop using it as your condition may get worse if stopped suddenly.

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

4 POSSIBLE SIDE EFFECTS

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

Stop using Beloderm and tell 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 Beloderm, have an infection or need other treatment.
- 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 Beloderm 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
- veins 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)
- increased blood sugar levels or sugar in the urine
- high blood pressure

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. By reporting side effects you can help provide more information on the safety of this medicine.

5 HOW TO STORE BELODERM

- Keep out of the sight and reach of children.
- Do not use this medicine after the expiry date which is stated on the tube or carton after (Exp).

The expiry date refers to the last day of that month.

- Do not store above 25°C.
- Do not throw away 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.

This leaflet was last revised in: July 2013