

Reason for Update: Project Pine – Update to Manufacturing Details
Market: Ireland
Agency Approval Date:
Text Date: 06/06/2022
Text Issue and Draft No.: Issue 10, Draft 1

Package leaflet: Information for the user

Betnovate Cream 0.1% w/w betamethasone (as 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.
- In this leaflet, Betnovate Cream 0.1% w/w will be called Betnovate.

What is in this leaflet

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

1 What Betnovate is and what it is used for

Betnovate contains the active substance betamethasone valerate which belongs to a group of medicines called corticosteroids that help to reduce redness, swelling and irritation of the skin in adults, the elderly and children over the age of 1 year. These should not be confused with “anabolic” steroids misused by some body builders and athletes and taken as tablets or injections.

Betnovate is used to help reduce the redness and itchiness of certain skin problems, such as:

- eczema
- prurigo nodularis (itchy nodules on the arms or legs)
- psoriasis (thickened patches of inflamed, red skin, often covered by silvery scales), excluding widespread plaque psoriasis
- lichen simplex chronicus (patches of thickened, itchy skin, caused by scratching)
- lichen planus (a skin disease that causes itchy, reddish-purple, flat-topped bumps on the wrists, forearms or lower legs)
- seborrhoeic dermatitis (a red, scaly, itchy rash that develops on the face, scalp, chest and back)
- discoid lupus erythematosus (a disease of the skin most often affecting the face, ears and scalp causing scarring and increased sensitivity of the affected skin to sunlight)

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- skin rash due to allergy or a substance that irritates your skin (irritant and allergic contact dermatitis)
- used in addition to oral or injectable steroids for erythroderma (inflammation, redness and scaling of the skin over most of the body)
- insect bites
- prickly heat
- dermatitis

For children over the age of 1 year, Betnovate is used for dermatitis that has not responded to milder steroid creams or ointments.

2 What you need to know before you use Betnovate

Do not use Betnovate:

- if you are allergic (hypersensitive) to betamethasone valerate or any of the other ingredients of Betnovate (listed in section 6).
- on a child under the age of 1 year.
- to treat any of the following skin problems, it could make them worse:
 - acne
 - rosacea (a facial skin condition where the nose, cheeks, chin, forehead or entire face are unusually red, with or without tiny visible blood vessels, bumps (papules) or pus-filled bumps (pustules))
 - spotty red rash around your mouth (perioral dermatitis)
 - itchy skin which is not inflamed
 - itching around the anus or genitals (penis or vagina)
 - infected skin (unless the infection is being treated with an anti-infective medicine at the same time)
 - widespread plaque psoriasis

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

Stop using Betnovate and tell your doctor as soon as possible if:

you find that you develop an allergic reaction, the area being treated becomes infected, or if you are being treated for psoriasis and you get raised bumps with pus under the skin (pustular psoriasis).

Warnings and precautions

Talk to your doctor or pharmacist before using Betnovate.

- If you are allergic (hypersensitive) to any corticosteroids.
- Only use an airtight dressing over this medicine if your doctor has told you to. If you are applying Betnovate under an airtight dressing, including a child's nappy, make sure that the skin is cleansed before a fresh dressing is applied to prevent infections. These dressings make it easier for the active ingredient to pass through the skin. It is possible to accidentally end up using too much. Prolonged use with occlusive dressings may cause the body to produce lower levels of the hormone cortisol than normal.

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- Take care when applying Betnovate to the face over a long period of time as it may cause skin thinning.
- Take care when applying Betnovate to the eyelids to make sure it does not get into your eye as there may be a risk of developing glaucoma.
- If you are using this for a prolonged period of time there is a possibility you may develop a cataract (clouding of the eye's lens).
- If you have psoriasis, your doctor will want to see you more often.
- Take care if you are using large quantities for a prolonged period or you are treating a large area of the body. This medicine may be absorbed through the skin and into your blood stream which can result in the following symptoms of hypercortisolism developing; stretch marks, the appearance of blood vessels under the surface of your skin, increased body hair growth, changes in skin colour, skin thinning, weight gain or rounding of the face (moon face).
- Only use Betnovate for as long as your doctor recommends. If your condition does not improve within 2 to 4 weeks of treatment, speak to your doctor.
- This medicine should not be used every day for more than 4 weeks at a time.
- Take care if you have eczema around a leg ulcer, use of a topical corticosteroid may increase the risk of an allergic reaction or an infection around the ulcer.
- 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.

Contact your doctor if you experience blurred vision or other visual disturbances.

Children

- Do not use this medicine on a child under the age of 1 year.
- Avoid continuous treatment for longer than 3 weeks or use of occlusion (including nappies) in infants and children under the age of 3 years as adrenocortical suppression (where the body produces lower levels of the hormone cortisol than normal) and growth retardation may occur.

Other medicines and Betnovate

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Some medicines may affect how Betnovate works or make it more likely that you'll have side effects. Examples of these medicines include:

- ritonavir and itraconazole

Tell your doctor or pharmacist if you are taking any of these.

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There are other medicines which may have a similar effect. It is therefore very important to **tell your doctor or pharmacist** if you're taking any other medicines, if you've taken any recently, or if you start taking a new one. This includes medicines 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.

You should not use this medicine if you pregnant or breast-feeding unless your doctor has recommended you to do so.

If you do use Betnovate when breast-feeding, **do not use it on your breast area** to ensure that the **baby does not accidentally get Betnovate in their mouth**.

Important information about some of the ingredients of Betnovate

Betnovate contains chlorocresol and cetostearyl alcohol.

Chlorocresol may cause allergic reactions and cetostearyl alcohol may cause local skin reactions (e.g. contact dermatitis).

3 How to use Betnovate

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 Betnovate once or twice a day. This may be reduced as your skin begins to get better, or your doctor may prescribe a weaker corticosteroid for you to use instead.
- This cream is for use on your skin only.
- Do not use more than the amount prescribed for you.
- If you are using an emollient (moisturising) preparation allow time for Betnovate to be absorbed after each application before applying the emollient.
- 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.
- If your eczema flares up frequently, your doctor may suggest that you use a less frequent dose of Betnovate once your eczema is under control, to help stop your eczema from coming back. For example, you may be advised to apply a thin film of Betnovate once daily, two times a week to areas of skin which have been affected by eczema, or to those areas where it is likely to reappear. Your doctor may also prescribe a weaker corticosteroid for you to use instead.
- 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.

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- 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.
- This medicine should not be used every day for more than 4 weeks at a time.

Guidance on how to apply the cream

- 1 Wash your hands.
- 2 Apply the cream sparingly to the affected area.
- 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.

Use in children

- Do not use this medicine on children under the age of 1 year.
- Avoid continuous treatment for longer than 3 weeks or use of occlusion (including nappies) in infants and children under the age of 3 years.

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 Betnovate 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 Betnovate than you should

If, by mistake on a few occasions you use more than you should, do not worry.

If you continue to use too much over a period of time you may develop symptoms such as: stretch marks, the appearance of blood vessels under the surface of your skin, increased body hair, changes to the colour of your skin, skin thinning, weight gain, moon face/rounding of the face.

If any of these symptoms occur or you think you have used too much of this medicine talk to your doctor or go to the hospital as soon as possible.

If you accidentally swallow Betnovate, it could make you ill. Rinse your mouth out with plenty of water and contact your doctor or pharmacist for advice.

If you forget to use Betnovate

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.

Do not apply extra Betnovate to make up for missed doses.

If you stop using Betnovate

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If you use Betnovate regularly make sure you talk to your doctor before you stop using it.

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. Side effects will affect your skin and may affect other parts of your body if a sufficient quantity of medicine is absorbed through the skin and enters your blood stream.

Stop using Betnovate and tell your doctor as soon as possible if:

- you find that your skin condition gets worse or becomes swollen during treatment. You may be allergic to the Betnovate, have an infection or need other treatment.
- you have psoriasis and you 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 Betnovate include:

Common: may affect up to 1 in 10 people

- local skin burning or pain
- itchy skin

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

Use of Betnovate for a long period of time, or use under an airtight dressing, may cause the following symptoms:

- increased weight
- rounding of the face/moon face
- obesity
- skin thinning, this may cause stretch marks and it may also damage more easily
- skin wrinkling
- skin dryness
- the appearance of blood vessels under the surface of your skin
- changes to the colour of your skin
- increased body hair growth
- hair loss/lack of hair growth/damaged looking hair

Other very rare skin reactions that may occur are:

- allergic reaction at the site of application
- worsening of condition
- application site irritation / pain
- redness

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- rash or hives
- skin infection

In children also look out for the following symptoms:

- delayed weight gain
- slow growth

Very rare side effects that may show up in blood tests or when your doctor gives you a medical examination:

- a decrease in the level of the hormone cortisol in your blood
- increased levels of sugar in your blood or urine
- high blood pressure
- cloudy lens in the eye (cataract)
- increased pressure in the eye (glaucoma)
- weakening of the bones through gradual loss of mineral (osteoporosis); additional tests may be needed after your medical examination to confirm if you have this condition

Not Known: frequency cannot be estimated from the available data

- blurred vision

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 Betnovate

- Keep this medicine out of the sight and reach of children.
- Do not use Betnovate after the expiry date which is stated on the tube end 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.

6 Contents of the pack and other information

What Betnovate contains

- The active substance is betamethasone (as valerate). Each 1 g contains 1 mg of betamethasone (0.1% w/w) as valerate.
- The other ingredients are: chlorocresol (see section 2), macrogol cetostearyl ether, cetostearyl alcohol (see section 2), white soft paraffin, liquid paraffin, sodium dihydrogen phosphate dihydrate, phosphoric acid, sodium hydroxide and purified water.

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What Betnovate looks like and contents of the pack

Betnovate is a white cream with a uniform appearance. Within each carton is a tube with a plastic screw cap, which contains either 30 g or 100 g of cream. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

GlaxoSmithKline (Ireland) Ltd, 12 Riverwalk, Citywest Business Campus, Dublin 24, Ireland.

Manufacturer

Delpharm Poznań Spółka Akcyjna, ul. Grunwaldzka 189, 60-322 Poznań, Poland.

GlaxoSmithKline Trading Services Limited, 12 Riverwalk, Citywest Business Campus, Dublin 24, Ireland

This leaflet was last revised in June 2022.

Other sources of information

This package leaflet is available in formats that are suitable for the blind or partially sighted. Such formats are available on request.

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