

Reason for update: Project Pine – Update to Manufacturing Details

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Package Leaflet: Information for the User

Betnovate-C 0.1% / 3% w/w Cream Betamethasone (as valerate) and Clioquinol

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

1 What Betnovate-C is and what it is used for

The name of your medicine is Betnovate-C Cream. Betnovate-C Cream (called 'Betnovate-C' in this leaflet) contains the active substances betamethasone valerate and clioquinol.

Betamethasone belongs to a group of medicines called corticosteroids that help to reduce redness, swelling and irritation of the skin. They should not be confused with "anabolic" steroids misused by some body builders and athletes and taken as tablets or injections.

Betnovate-C also contains clioquinol, an anti-infective agent, which may help to prevent or clear up some bacterial and fungal infections of the skin.

Betnovate-C is a strong and rapidly effective treatment for inflamed skin conditions in which infection may be a problem, 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)

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- skin rash due to allergy or a substance that irritates your skin (irritant and allergic contact dermatitis)
- reactions to insect bites
- prickly heat
- anal and genital intertrigo (skin irritation in the anal or genital area (penis or vagina) where skin rubs against skin, or other material)
- otitis externa (inflamed, red, flaky skin of the outer ear and ear canal).

2 What you need to know before you use Betnovate-C

Do NOT use Betnovate-C:

- if you are allergic to betamethasone valerate, clioquinol, iodine or any of the other ingredients of this medicine (listed in Section 6)
- on a child under 2 years of age
- to treat any of the following skin problems, it could make them worse:
 - widespread plaque psoriasis
 - acne
 - 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) (rosacea)
 - 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 caused by bacterial infection (such as impetigo or tuberculosis)
 - fungal infections, such as ringworm, athlete's foot or thrush
 - viral infections, such as cold sores, herpes or chicken pox.

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-C.

Stop using Betnovate-C 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-C.

- Only use an airtight dressing over this medicine if your doctor has told you to. If you are applying Betnovate-C 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.
- Take care if you have ever had an allergy to any creams or ointments in the past.
- Take care when applying Betnovate-C to the face over a long period of time as it may cause skin thinning.

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- Take care when applying Betnovate-C to the eyelids to make sure it does not get into your eye as there may be a risk of developing glaucoma (increased pressure in the eye) or cataract (clouding of the eye's lens) from repeated exposure.
- If you have psoriasis, your doctor will want to see you more often.
- 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).
- Prolonged use or use under occlusive dressings may result in damage to the nervous system.
- If you have eczema around a leg ulcer, using a topical corticosteroid may increase the risk of an allergic reaction or an infection around the ulcer.
- Take care when applying as the cream may stain hair, skin or clothing. Cover application with dressing to protect clothing.
- Do not dilute Betnovate-C.

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

Children

- Do not use this medicine on a child under 2 years of age.
- Avoid long-term continuous treatment in infants and children over 2 years of age with or without an occlusive dressing or nappy as adrenocortical suppression (where the body produces lower levels of the hormone cortisol than normal) and growth retardation may occur.

Other medicines and Betnovate-C

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription. This includes herbal medicines.

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

- ritonavir and itraconazole
- vigabatrin

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 are pregnant or breast-feeding unless your doctor has recommended you to do so.

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

Betnovate-C contains chlorocresol and cetostearyl alcohol

Betnovate-C contains chlorocresol and cetostearyl alcohol; chlorocresol may cause allergic reactions and cetostearyl alcohol may cause local skin reactions (e.g. contact dermatitis).

Whilst using Betnovate-C do not smoke or go near naked flames due to the risk of severe burns. Fabric (clothing, bedding, dressing 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.

3 How to use Betnovate-C

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-C 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.
- If you are also using an emollient (moisturiser), allow time for Betnovate-C to be absorbed into your skin before applying the emollient.
- 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 gets worse or does not improve within 2 to 4 weeks, talk to your doctor.

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.

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Use in children

- Do not use it on children under 2 years of age.
- Avoid long-term continuous treatment in infants and children over 2 years of age with or without an occlusive dressing or nappy as adrenocortical suppression (where the body produces lower levels of the hormone cortisol than normal) and growth retardation may occur.

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 use more Betnovate-C 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 forget to use Betnovate-C

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-C to make up for missed doses.

If you stop using Betnovate-C

If you use Betnovate-C 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.

Stop using Betnovate-C 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-C, have an infection or need other treatment. This can happen very rarely during treatment.
- you have psoriasis you may get raised bumps with pus under the skin. This can happen rarely during or after treatment and is known as pustular psoriasis.

Other side effects you may notice when using Betnovate-C include:
Common (affects less than 1 in 10 people)

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- local skin burning or pain
- itchy skin

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

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

- stretch marks may develop
- the appearance of blood vessels under the surface of your skin
- increased body hair growth
- changes in skin colour
- thinning of your skin and it may also damage more easily
- skin wrinkling
- skin dryness
- weight gain / obesity
- rounding of the face (moon face)
- 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 or pain
- redness
- rash or hives
- skin infection
- hair discolouration

The following very rare side effects may also occur in children:

- 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

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If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRAs 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-C

- Keep this medicine out of the sight and reach of children.
- Do not use Betnovate-C 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 30°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-C cream contains

- The active ingredients are betamethasone (as valerate) and clioquinol. Each 1 g contains 1 mg of betamethasone (0.1% w/w) as valerate and 30 mg of clioquinol (3% w/w).
- The other ingredients are chlorocresol (see section 2), cetomacrogol 1000, cetostearyl alcohol (see section 2), white soft paraffin, liquid paraffin (see section 2), sodium dihydrogen phosphate dihydrate, phosphoric acid, sodium hydroxide and purified water.

What Betnovate-C 0.1% w/w looks like and contents of the pack

Within each carton is a tube with a plastic screw cap, which contains 30 g of a pale yellow cream.

Marketing Authorisation Holder and Manufacturer

Product Authorisation Holder:

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

Manufacturer:

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

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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