

PATIENT INFORMATION LEAFLET: INFORMATION FOR THE USER

BETNOVATE-C CREAM

0.1% W/W BETAMETHASONE 17-VALERATE WITH 3% W/W CLIOQUINOL CREAM

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 health care provider.
- 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 becomes serious, or if you notice any side effects not listed in this leaflet, please tell your health care provider.

In this leaflet:

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

1. WHAT BETNOVATE-C IS AND WHAT IT IS USED FOR

The name of your medicine is Betnovate-C cream. Betnovate-C contains betamethasone valerate which belongs to a group of medicines called steroids and clioquinol which is an antimicrobial agent.

Steroids help to reduce redness, swelling and irritation of the skin. Antimicrobial agents help to treat microbial infections.

Betnovate-C relieves the symptoms of certain skin problems which may be infected:

- eczema
- prurigo nodularis (itchy nodules on the arms or legs)
- psoriasis (thickened patches of inflamed, red skin, often covered by silvery scales)
- 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)
- skin rash due to allergy or a substance that irritates your skin (irritant and allergic contact dermatitis)
- anal or genital intertrigo (skin irritation in the anal or genital area where skin rubs against skin, clothing, or other material)
- otitis externa (inflamed, red, flaky skin of the outer ear and ear canal)
- insect bites
- prickly heat

2. BEFORE YOU USE BETNOVATE-C

Do not use Betnovate-C

- on children under 1 year
 - to treat any of the following skin problems - it could make them worse:
 - viral infections such as cold sores, herpes or chicken pox
 - fungal infections such as ringworm, athlete's foot, or thrush
 - 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))
 - rashes around the mouth
 - itchy skin which is not inflamed
 - itching around the anus or genitals (penis and vagina)
- If you think any of these apply to you, don't use Betnovate-C until you have checked with your doctor or pharmacist.

Take special care with BETNOVATE-C

- Tell your doctor if you are allergic (hypersensitive) to Betnovate-C or any of the ingredients (listed in Section 6), or to iodine.
- Don't dilute Betnovate-C.
- Only use Betnovate-C for as long as your doctor recommends. If your condition does not improve after 2 to 4 weeks of treatment, speak to your doctor.
- Take care when applying Betnovate-C to the eyelids to make sure it does not get into your eye.
- If you experience blurred vision or other visual disturbances, speak to your doctor.
- Take care when applying Betnovate-C to the face over a long period of time as it may cause skin thinning.
- 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.
- 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 an infant's nappy, make sure that the skin is

cleansed before a fresh dressing is applied, to prevent infections.

- Betnovate-C may stain hair, skin or fabric. Cover application with dressing to protect clothing.

→ Contact your doctor if an infection develops (See Section 4 Possible Side Effects).

Other medicines and Betnovate-C

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

→ **Tell your doctor or pharmacist** if you are taking any of these. There are other medicines which may have a similar effect. It's 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 think you could be**, or if you are **planning to become pregnant, don't use** Betnovate-C without talking to your doctor first.

If you are breast-feeding, you must check with your doctor before you use Betnovate-C.

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

3. HOW TO USE BETNOVATE-C

Always use Betnovate-C **exactly as your doctor has told you**. Check with your doctor or pharmacist if you are not sure.

How much to use

- Use Betnovate-C once or twice a day. Your doctor will tell you how often to use this medicine. The number of times you use your medicine may be reduced as your skin gets better. Your doctor may also prescribe a weaker steroid for you to use instead.

How to use Betnovate-C

- Apply a thin layer and gently rub in, using only enough to cover the entire affected area.
- Wash your hands after use unless treating the hands.
- If you are also using an emollient (moisturising) preparation allow time Betnovate-C for to be absorbed after each application before applying the emollient.
- This medicine should not be used every day for more than 4 weeks at a time.

If you forget to use Betnovate-C

- If you forget to use Betnovate-C apply it as soon as you remember, then continue as before.
- Do not apply extra Betnovate-C to make up for missed doses.

Don't stop using Betnovate-C without advice

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

If you use too much Betnovate-C

- If you apply a large amount of Betnovate-C or accidentally swallow a lot of Betnovate-C, it could make you ill. If you do swallow a large amount of Betnovate-C, rinse your mouth out with plenty of water and contact your doctor or pharmacist for advice.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Betnovate-C 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.

If your skin condition gets worse or your skin becomes swollen during treatment, you may be allergic to the medicine, have an infection or need other treatment.

→ Stop using Betnovate-C and tell your doctor as soon as possible.

Common side effects

These may affect up to 1 in 10 people

- itchy skin
- local skin burning or pain

Very rare side effects

These may affect up to 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:

- increased weight
- moon face / rounding of the face
- obesity
- skin thinning - this may cause stretch marks
- 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
- 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
- redness
- rash or hives
- if you have psoriasis you may get raised bumps with pus under the skin. This can happen very rarely during or after treatment and is known as pustular psoriasis
- skin infection
- hair discoloration.

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.

If you get side effects

→ **Tell your doctor or pharmacist** if any of the side effects listed become **severe or troublesome**, or if you notice any side effects not listed in this leaflet.

5. HOW TO STORE BETNOVATE-C

Keep out of the reach and sight of children. It may harm them

Store below 30°C

Don't use Betnovate-C after the expiry date on the tube or carton (Exp).

Don't dispose of medicines in wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. This will help protect the environment.

6. FURTHER INFORMATION

What Betnovate-C cream contains:

- The active ingredients are betamethasone valerate and clioquinol

Each 1 g contains 1 mg of betamethasone valerate (0.1% w/w).and 30 mg (3% w/w) of clioquinol.

The other ingredients are:

Chlorocresol

Macrogol cetostearyl ether
Cetostearyl alcohol
White soft paraffin
Liquid paraffin
Sodium dihydrogen
Phosphate dihydrate
Phosphoric acid
Sodium hydroxide
Purified Water.

What Betnovate-C looks like and contents of the pack:

Betnovate-C cream is packed in collapsible aluminium tubes, internally coated with an epoxy resin-based lacquer and closed with a cap.

Manufacturer

Glaxo Operations UK Ltd, Harmire Road, Barnard Castle, Durham DL 12 8DT, UK.

This leaflet was last approved on

11/2019