

Package leaflet: Information for the patient

Betamethasone valerate/Clioquinol 1 mg/30 mg/g Cream

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 Betamethasone/Clioquinol Cream is and what it is used for
2. What you need to know before you use Betamethasone/Clioquinol Cream
3. How to use Betamethasone/Clioquinol Cream
4. Possible side effects
5. How to store Betamethasone/Clioquinol Cream
6. Contents of the pack and other information

1. What Betamethasone/Clioquinol Cream is and what it is used for

Betamethasone/Clioquinol Cream contains two different medicines called betamethasone valerate and clioquinol.

- Betamethasone valerate belongs to a group of medicines called steroids. It helps to reduce swelling and irritation.
- Clioquinol is a type of anti-infective medicine. It fights bacterial and fungal infections of the skin.

This medicine is used to help reduce the redness and itchiness of certain skin problems. These skin problems include eczema, psoriasis, dermatitis or insect bites, where an infection may be a problem.

2. What you need to know before you use Betamethasone/Clioquinol Cream

Do not use Betamethasone/Clioquinol Cream:

- if you are allergic to betamethasone valerate, clioquinol or any of the other ingredients (listed in section 6)
- if you are allergic to iodine
- on a child under 2 years old
- 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)
 - itchy skin which is not inflamed
 - viral infections, such as cold sores, herpes or chicken pox
 - blisters or sores on your face and hands (impetigo), or other bacterial infections
 - fungal infections, such as ringworm, athlete's foot or thrush
 - itching around your back passage (anus) or private parts (genitals) - unless your doctor has told you to do so.

If any of the above apply to you, speak to your doctor or pharmacist.

Warnings and precautions

Talk to your doctor or pharmacist before using Betamethasone/Clioquinol Cream if

- you are applying the cream 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 Betamethasone/Clioquinol Cream to the face over a long period of time as it may cause skin thinning.
- take care when applying the cream 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.
- 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.
- 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 Betamethasone/Clioquinol Cream.

If there is a worsening of your condition during use consult your prescriber – you may be experiencing an allergic reaction, have an infection or your condition requires a different treatment. If you experience a recurrence of your condition shortly after stopping treatment, within 2 weeks, do not restart using the cream without consulting your prescriber unless your prescriber has previously advised you to so. If your condition has resolved and on recurrence the redness extends beyond the initial treatment area and you experience a burning sensation, please seek medical advice before restarting treatment.

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.

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

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 Betamethasone/Clioquinol Cream

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

Some medicines may affect how Betamethasone/Clioquinol Cream 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.

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

Driving and using machines

Betamethasone/Clioquinol Cream is unlikely to affect your ability to operate machinery or to drive.

Betamethasone/Clioquinol Cream contains chlorocresol and cetostearyl alcohol including cetyl alcohol

This medicine contains chlorocresol, which may cause allergic reactions. This medicine also contains cetostearyl alcohol including cetyl alcohol, which may cause local skin reactions (e.g. contact dermatitis).

3. How to use Betamethasone/Clioquinol Cream

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 the cream 2 or 3 times 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 after 7 days talk to your doctor.**
- Do not mix with any other creams or ointments.

Guidance on how to apply the cream

1. Wash your hands.
2. Gently rub the correct amount of cream into the skin until it has all disappeared. You can measure how much cream to use with your fingertip. 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

You should find that:

- two fingertips of cream will cover both hands or one foot
- three fingertips of cream will cover one arm
- six fingertips of cream will cover one leg
- fourteen fingertips of cream will cover the front and back of the body.

Do not worry if you find you need a little more or a little less than this. It is only a rough guide.

For a child

- Do not use it on children under 1 year of age.
- The smaller the child the less you will need to use.
- A child of 4 years needs about a third of the adult 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 apply Betamethasone/Clioquinol Cream 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 Betamethasone/Clioquinol Cream than you should

If, by mistake on a few occasions you use more than you should, do not worry. If you apply a lot or if 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/Clioquinol Cream

If you forget to use the cream, use it as soon as you remember, but if it is almost time for your next dose, skip the missed dose and continue as usual. Do not use a double dose to make up for a forgotten dose.

If you stop using Betamethasone/Clioquinol Cream

If you use this medicine regularly make sure you talk to your doctor before you stop using it. If you have any further questions on the use of this product, 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 this medicine and tell your doctor as soon as possible if:

- you find that your condition gets worse or becomes swollen during treatment. You may be allergic to the cream, 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 Betamethasone/Clioquinol Cream include:**Common** (affects less than 1 in 10 people)

- local skin burning or pain
- itchy skin

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

Use of Betamethasone/Clioquinol Cream 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

Steroid withdrawal reaction: If used continuously for prolonged periods a withdrawal reaction may occur on stopping treatment with some or all of the following features: redness of the skin which can extend beyond the initial area treated, a burning or stinging sensation, intense itching, peeling of the skin, oozing open sores.

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 Website:

www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Betamethasone/Clioquinol Cream

Keep this medicine out of the sight and reach of children.

Do not use this medicine 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 any 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 Betamethasone/Clioquinol Cream contains

- The active substances are betamethasone valerate and clioquinol. Each 1 gram of cream contains 1.22 mg betamethasone valerate (equivalent to 1.0 mg betamethasone) and 30 mg clioquinol.
- The other ingredients are chlorocresol, cetomacrogol 1000, cetostearyl alcohol, white soft paraffin, liquid paraffin, sodium acid phosphate, phosphoric acid, sodium hydroxide and purified water. (See end of section 2 for further information on chlorocresol and cetostearyl alcohol including cetyl alcohol).

What Betamethasone/Clioquinol Cream looks like and contents of the pack

Within each carton is a tube with a plastic screw cap, which contains 15 g or 30 g of cream.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Essential Generics, 8a Egham Business Village, Crabtree Road, Egham, Surrey TW20 8RN, United Kingdom.

Manufacturer

Purna Pharmaceuticals NV, Rijksweg 17, 2870 Puurs, Belgium.

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