

Package leaflet: Information for the patient

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

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

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

Betamethasone/Clioquinol Ointment 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 Ointment

Do not use Betamethasone/Clioquinol Ointment:

- 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 1 year 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)
 - 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 Ointment if

- you are applying the ointment 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.

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 ointment 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.

Staining of your hair, skin and clothes can occur. You can protect clothes by covering the treated area with a cotton bandage or piece of clean cloth.

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.

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 Betamethasone/Clioquinol Ointment

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.

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.

Driving and using machines

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

3. How to use Betamethasone/Clioquinol Ointment

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 ointment 2 or 3 times a day. This may be reduced as your skin begins to get better.
- This ointment 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 ointment 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 ointment

1. Wash your hands.
2. Gently rub the correct amount of ointment into the skin until it has all disappeared. You can measure how much ointment to use with your fingertip. This picture shows one fingertip unit.
3. Unless you are meant to apply the ointment to your hands as a part of the treatment, wash them again after using the ointment.

For an adult

You should find that:

- two fingertips of ointment will cover both hands or one foot
- three fingertips of ointment will cover one arm
- six fingertips of ointment will cover one leg
- fourteen fingertips of ointment 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 Ointment to your face

You should only apply the ointment 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 ointment get into your eyes.**

If you use more Betamethasone/Clioquinol Ointment 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 Ointment

If you forget to use the ointment, 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 Ointment

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 ointment or need other treatment.

Other side effects you may notice when using Betamethasone/Clioquinol Ointment include:

- a feeling of burning, irritation or itching where the ointment is applied.

- if you have psoriasis you may get raised bumps with pus under the skin. This can happen during or after the treatment and is known as pustular psoriasis.

Side effects if you use Betamethasone/Clioquinol Ointment for a long time, or you use a lot each time you apply it, or you apply it under an airtight dressing or a nappy:

- stretch marks may develop
- veins under the surface of your skin may become more noticeable
- increased hair growth and changes in skin colour
- thinning of your skin that may also damage more easily
- weight gain, rounding of the face and high blood pressure. These are more likely to happen in infants and children.

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 Ointment

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 Ointment contains

- The active substances are betamethasone valerate and clioquinol. Each 1 gram of ointment contains 1.22 mg betamethasone valerate (equivalent to 1.0 mg betamethasone) and 30 mg clioquinol.
- The other ingredients are: white soft paraffin and liquid paraffin.

What Betamethasone/Clioquinol Ointment 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 ointment.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Essential Generics, 7 Egham Business Village, Crabtree Road, Egham, Surrey TW20 8RB, United Kingdom.

Manufacturer

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

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