

Package leaflet: Information for the patient

Beclometasone dipropionate 0.25 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 Beclometasone dipropionate 0.25 mg/g Ointment is and what it is used for
2. What you need to know before you use Beclometasone dipropionate 0.25 mg/g Ointment
3. How to use Beclometasone dipropionate 0.25 mg/g Ointment
4. Possible side effects
5. How to store Beclometasone dipropionate 0.25 mg/g Ointment
6. Contents of the pack and other information

1. What Beclometasone dipropionate 0.25 mg/g Ointment is and what it is used for

Beclometasone dipropionate Ointment contains a medicine called beclometasone dipropionate. It belongs to a group of medicines called steroids. It helps to reduce swelling and irritation. This medicine is used to help reduce the redness and itchiness of certain skin problems. These skin problems include eczema, psoriasis or dermatitis.

2. What you need to know before you use Beclometasone dipropionate 0.25 mg/g Ointment

Do not use Beclometasone dipropionate 0.25 mg/g Ointment:

- if you are allergic to beclometasone dipropionate or any of the other ingredients (listed in section 6)
- on the eyes
- 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)
 - itching around your back passage or private parts - unless your doctor has told you to do so
- viral infections, such as cold sores, herpes or chicken pox
 - fungal infections, such as ringworm, athlete's foot or thrush
 - skin blisters or sores that are caused by an infection
 - varicose ulcers (ulcers caused by swollen veins)
 - stasis ulcers (ulcers caused by reduced blood or body fluid flow)

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 Beclometasone dipropionate 0.25 mg/g 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 ointment
- if 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.

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 Beclometasone dipropionate 0.25 mg/g Ointment

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.

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

Beclometasone dipropionate 0.25 mg/g Ointment is unlikely to affect your ability to operate machinery or to drive.

Beclometasone dipropionate 0.25 mg/g Ointment contains propylene glycol

This medicine contains 50 mg propylene glycol in each gram ointment. May cause skin irritation.

3. How to use Beclometasone dipropionate Ointment 0.25 mg/g

Always use this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

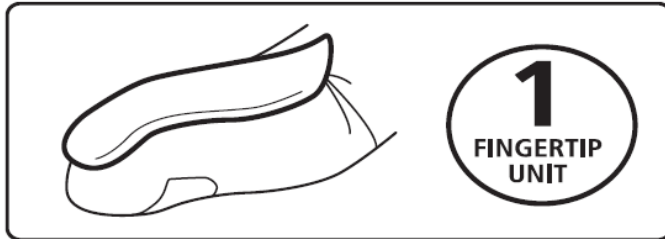
Using this medicine

- You usually apply the ointment twice a day. This may be reduced as your skin begins to get better.
- **If your skin problem does not improve after 2 to 4 weeks talk to your doctor.**
- This ointment is for use on your skin only.
- 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 and moist conditions under 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.
- 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.



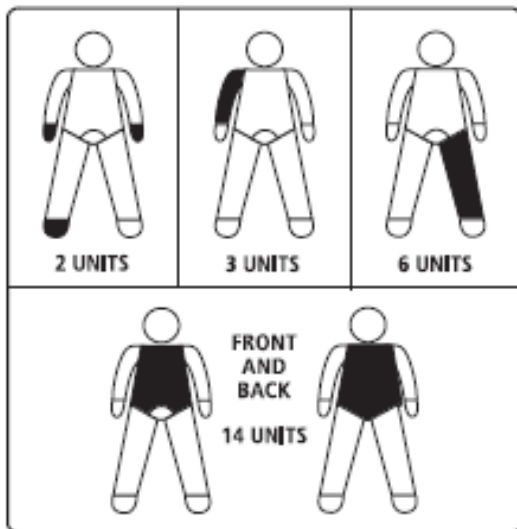
3. Unless you are meant to apply the ointment to your hands as a part of the treatment, wash them again after using the ointment.

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.

Your doctor may suggest applying the ointment under an airtight dressing. It will only be to help the ointment to start working. After a short period of time you will then apply the ointment as normal.

If you apply Beclometasone dipropionate 0.25 mg/g Ointment to your face

You should only apply the ointment to your face if your doctor tells you to and for **not more than 5 days**. Do not cover the treated area with a dressing, as the skin on your face thins easily. **Do not let the ointment get into your eyes**. If it does, wash it out with plenty of water.

How long

You should stop using the ointment as soon as the skin problem is better.

Sometimes only a few days treatment is needed. If there is no improvement after 2 to 4 weeks, see your doctor again. If the doctor recommends that you continue to use the ointment, you should never use it for more than 4 weeks without seeing your doctor again.

If your doctor has prescribed the ointment for psoriasis you should let your doctor review your progress at regular intervals, as such treatment needs careful supervision.

If you use more Beclometasone dipropionate 0.25 mg/g 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.

1. Tell your doctor, pharmacist or nearest hospital casualty department immediately.
2. Take the ointment tube with you so that people can see what you have used or taken.
3. Do this even if you feel well.

If you forget to use Beclometasone dipropionate 0.25 mg/g 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 Beclometasone dipropionate 0.25 mg/g Ointment

If you use Beclometasone dipropionate Ointment 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 Beclometasone dipropionate 0.25 mg/g Ointment and tell your doctor as soon as possible if:

- you find that your skin problem gets worse. You may be allergic to the ointment or have a skin infection which needs other treatment.

Other side effects you may notice when using Beclometasone dipropionate 0.25 mg/g Ointment include:

- a feeling of burning, irritation or itching where the ointment is applied. These may be similar to the skin condition being treated
- 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 this medicine 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 and it damages 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.

If you absorb or swallow this medicinal product in large quantities, it can make you ill. This is unlikely when you use the ointment normally.

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 at: 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 Beclometasone dipropionate 0.25 mg/g 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 and on the carton after EXP. The expiry date refers to the last day of that month.

- Do not store above 25°C. Store in the original package in order to protect from light.

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 Beclometasone dipropionate 0.25 mg/g Ointment contains

- The active substance is beclometasone dipropionate. Each 1 g contains 0.25 mg of beclometasone (0.025% w/w) as dipropionate

- The other ingredients are propylene glycol and white soft paraffin. (See end of section 2 for further information on propylene glycol).

What Beclometasone dipropionate 0.25 mg/g Ointment looks like and contents of the pack

Within each carton is an aluminium tube with a plastic screw cap, which contains 15 g, 30 g or 50 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.

Manufacturer

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

This leaflet was last revised in September 2021.