

Package leaflet: Information for the patient

Clobetasol propionate/neomycin sulfate/nystatin 0.5 mg/5 mg/100,000 IU/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 Clobetasol/neomycin/nystatin Cream is and what it is used for
2. What you need to know before you use Clobetasol/neomycin/nystatin Cream
3. How to use Clobetasol/neomycin/nystatin Cream
4. Possible side effects
5. How to store Clobetasol/neomycin/nystatin Cream
6. Contents of the pack and other information

1. What Clobetasol/neomycin/nystatin Cream is and what it is used for

Clobetasol/neomycin/nystatin Cream contains clobetasol propionate, neomycin sulfate and nystatin.

- Clobetasol propionate belongs to a group of medicines called steroids. It helps to reduce swelling and irritation of the skin.
- Neomycin sulfate and nystatin are anti-infective medicines. They fight 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 or psoriasis, where an infection may be a problem.

2. What you need to know before you use Clobetasol/neomycin/nystatin Cream

Do not use Clobetasol/neomycin/nystatin Cream:

- if you are allergic to clobetasol propionate, neomycin sulfate, nystatin or any of the other ingredients of this medicine (listed in section 6)
- if you have a peanut or soya allergy
- 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)
 - 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, athletes foot or thrush
 - skin blisters or sores that are caused by an infection

- outer ear infections when the ear drum is perforated.

If any of the above apply to you, or if you are not sure, speak to your doctor or pharmacist.

Warnings and precautions

Talk to your doctor or pharmacist before using your Clobetasol/neomycin/nystatin Cream:

- if you have previously had an allergic reaction with another steroid
- if you are applying the cream 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 cream
- if you have psoriasis. Your doctor will want to see you more often
- if you are applying the cream on broken skin or within the skin folds
- if you are using the cream for a chronic leg ulcer as you may be at increased risk of local allergic reaction or infection
- if you are applying to a large surface area or within the skin folds
- if you are applying near eyes or on eyelids, as cataracts or glaucoma may result if the cream repeatedly enters the eye
- if you are applying to thin skin such as the face or on children as their skin is thinner than adults and as a result may absorb larger amounts. Use on children should be limited to 5 days and reviewed weekly. Use on the face should be limited to only a few days.
 - Dressing or bandages should not be used on children or on the face where the cream is applied
- if you have kidney problems. Your doctor may decide to change the amount or number of times you apply the cream.
- if you experience newly developed bone pain or worsening of previous bone symptoms during a treatment with Clobetasol/neomycin/nystatin Cream, especially if you have been using Clobetasol/neomycin/nystatin Cream for a prolonged time or repeatedly.
- if you use other oral/topical medication containing corticosteroids or medication intended to control your immune system (e.g. for autoimmune disease or after a transplantation). Combining Clobetasol/neomycin/nystatin Cream with these medicines may result in serious infections.

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 do 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 Clobetasol/neomycin/nystatin Cream

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, especially if you are taking ritonavir and itraconazole medications. Please also tell your doctor or pharmacist if you are taking medicines obtained without a prescription, or herbal preparations.

If the cream is absorbed into the body in large amounts, the effects of medicines used to relax muscles during surgery can last longer or even be increased. If you are having surgery you should tell the doctor that you have used Clobetasol/neomycin/nystatin Cream.

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

Clobetasol/neomycin/nystatin Cream is unlikely to affect your ability to operate machinery or to drive.

Clobetasol/neomycin/nystatin Cream contains arachis (peanut) oil

Clobetasol/neomycin/nystatin Cream contains arachis oil (peanut oil). If you are allergic to peanut or soya, do not use this medicinal product.

3. How to use Clobetasol/neomycin/nystatin Cream

Always use the cream exactly as your doctor has told you and always read the label. Your doctor will decide on the appropriate dose to suit your condition. Check with your doctor or pharmacist if you are not sure.

Using this medicine

- You usually apply the cream 1 or 2 times a day. This may be reduced as your skin begins to get better.
- **If your skin problem does not improve after 7 days talk to your doctor.**
- This cream 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 cream 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 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.



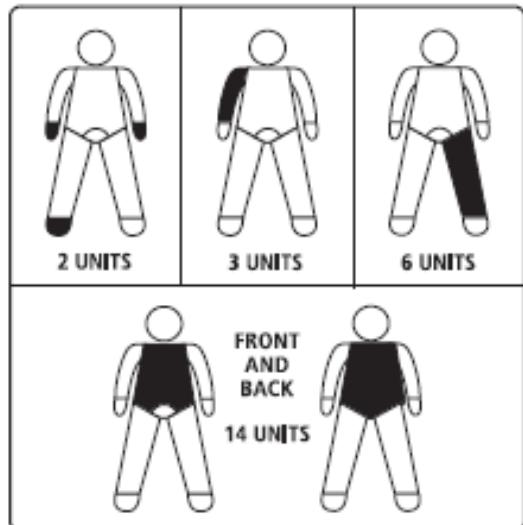
3. Unless you are meant to apply the cream to your hands as a part of the treatment, wash them again after using the cream.

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 2 years 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 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 apply Clobetasol/neomycin/nystatin Cream to your face

You should only apply the cream 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 cream get into your eyes**. If it does, wash it out with plenty of water.

How long

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

Sometimes only a few days treatment is needed. If there is no improvement after 7 days, see your doctor again. If the doctor recommends that you continue to use the cream, you should never use it for more than 4 weeks without seeing your doctor again.

The maximum weekly dose should not exceed 50 g/week.

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

If you use more Clobetasol/neomycin/nystatin 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.

1. Tell your doctor, pharmacist or nearest hospital casualty department immediately.
2. Take the cream 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 Clobetasol/neomycin/nystatin Cream

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 use a double dose to make up for a forgotten dose.

If you stop using Clobetasol/neomycin/nystatin Cream

If you use Clobetasol/neomycin/nystatin Cream 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. Do not be alarmed by this list of possible side effects. You may not experience any of them.

STOP using Clobetasol/neomycin/nystatin Cream and tell your doctor as soon as possible if:

- you find that your skin problem gets worse or becomes swollen during treatment. You may be allergic to the cream or have a skin infection which needs other treatment.
- you have psoriasis and get raised bumps with pus under the skin. This can happen during or after the treatment and is known as pustular psoriasis.

Other side effects you may notice when using Clobetasol/neomycin/nystatin Cream include:

Common (may affect up to 1 in 10 people)

- Veins under the surface of your skin may become more noticeable
- Thinning of your skin

Uncommon (may affect up to 1 in 100 people)

- Stretch marks may develop

Very rare (may affect up to 1 in 10,000 people)

- An increased risk of infection
- An allergic skin reaction where the cream is applied
- A feeling of burning, pain, irritation or itching where the cream is applied
- Rash, itchy bumpy skin or redness of the skin
- Thinning and dryness of your skin and it may also damage or wrinkle more easily
- An increase or reduction in hair growth or hair loss and changes in skin colour
- Weight gain, rounding of the face
- Delayed weight gain or slowing of growth in children

- Bones can become thin, weak and break easily
- Cloudy lens in the eye (cataract) or increased pressure in the eye (glaucoma)
- Increased blood sugar levels or sugar in the urine
- High blood pressure.

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 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 Clobetasol/neomycin/nystatin 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 and on the carton. The expiry date refers to the last day of that month.
- Do not store above 25°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 Clobetasol/neomycin/nystatin Cream contains

- The active substances are: clobetasol propionate (0.5 mg in 1 g of cream), neomycin sulfate (5 mg in 1 g of cream), nystatin (100,000 IU in 1 g of cream).
- The other ingredients are: propyl gallate, titanium dioxide, polyoxyethylene cetyl ether, arachis oil (peanut oil), white beeswax or beeswax substitute, microcrystalline wax and light liquid paraffin. (See end of section 2 for further information on arachis oil).

What Clobetasol/neomycin/nystatin Cream looks like and contents of the pack

Clobetasol/neomycin/nystatin Cream is a smooth yellow-brown cream.

It is available in aluminium tubes of 25 g or 30 g.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Essential Generics, 8a Crabtree Road, Egham, Surrey, TW20 8RN.

Manufacturer

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

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