

Dermovate-NN Cream



clobetasol propionate, neomycin sulphate, nystatin

100/L/m/5a

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 doctor or pharmacist.
- 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 get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

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

1. What this medicine is and what it is used for

Dermovate-NN cream contains clobetasol propionate, neomycin sulphate and nystatin.

- Clobetasol propionate belongs to a group of medicines called steroids. It helps to reduce swelling and irritation of the skin.
- Neomycin sulphate and nystatin are anti-infective medicines. They fight bacterial and fungal infections of the skin.

Dermovate-NN 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. Before you use

Do not use Dermovate-NN:

- if you are allergic (hypersensitive) to clobetasol propionate, neomycin sulphate, nystatin or to any of the other ingredients (see 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, athlete's 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.

Take special care with Dermovate-NN

Check with your doctor or pharmacist before using your medicine if you:

- have previously had an allergic reaction with another steroid
- 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
- have psoriasis. Your doctor will want to see you more often
- are applying the cream on broken skin or within the skin folds
- are using the cream for a chronic leg ulcer as you may be at increased risk of local allergic reaction or infection
- are applying to a large surface area or within the skin folds
- you are applying near eyes or on eyelids, as cataracts or glaucoma may result if the cream repeatedly enters the eye
- 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

- have kidney problems. Your doctor may decide to change the amount or number of times you apply the cream.

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

Taking other medicines

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 Dermovate-NN 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 Dermovate-NN.

Pregnancy and breast-feeding

Talk to your doctor or pharmacist before using this medicine if you are pregnant, might become pregnant or are breast-feeding.

Driving and using machines

Dermovate-NN is unlikely to affect your ability to operate machinery or to drive.

Important information about some of the ingredients of Dermovate-NN Cream

- **arachis (peanut) oil**
If you are allergic to peanut or soya, do not use this medicine.

3. How to use

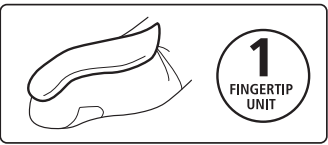
Always use Dermovate-NN exactly as your doctor has told you and always read the label. Your doctor will decide on the appropriate dose to suit your condition. Ask your doctor or pharmacist if you are not sure.

Using this medicine

- You usually apply Dermovate-NN 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 Dermovate-NN 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

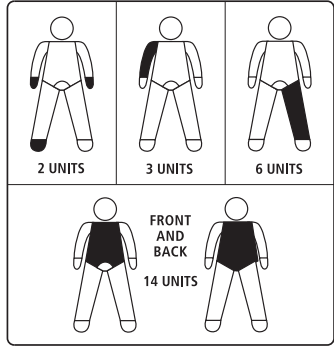
You should find that:

- two fingertips of cream will cover both hands or one foot

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- 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 Dermovate-NN 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 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

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 missed dose.

If you stop using

If you use Dermovate-NN 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, Dermovate-NN 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 Dermovate-NN 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 Dermovate-NN 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.

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

5. How to store

- Keep out of the reach and sight of children.
- Do not use 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 it away with your household waste or in water. Return all the unwanted medicine to your pharmacist. This will help to protect the environment.

6. Further information

What Dermovate-NN Cream contains

- The active ingredients are:
 - clobetasol propionate (0.5 mg in 1 g of cream), neomycin sulphate (5 mg in 1 g of cream), nystatin (100,000 units 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 Dermovate-NN Cream looks like and contents of the pack

Dermovate-NN 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

Chemidex Pharma Ltd, Chemidex House, Egham Business Village, Crabtree Road, Egham, Surrey, TW20 8RB.

Manufacturers

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

This leaflet was last revised in

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