

**PATIENT PACKAGE INSERT
IN ACCORDANCE WITH THE
PHARMACISTS' REGULATIONS
(PREPARATIONS)-1986**

This medicine is dispensed with a doctor's prescription only

Neriderm Cream Neriderm Ointment Diflucortolone Valerate 0.1 gr/100 gr

Inactive ingredients and allergens in the medicine - see section 2 "Important information about some of the ingredients of the medicine" and section 6 in the leaflet.

Read this entire leaflet carefully before you start using the medicine. This leaflet contains concise information about the medicine. If you have any further questions, refer to the doctor or pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It might harm them, even if you think that their medical condition is similar.

1. What is the medicine intended for?

Neriderm is intended for the treatment of corticosteroid responsive dermatoses in the absence of infection.

Therapeutic group:
Topical corticosteroids.

Neriderm contains the active ingredient diflucortolone valerate which is a topical (for application to the skin) corticosteroid (or steroid). Corticosteroids of this type are used to reduce redness and itching that are caused by different skin problems.

Neriderm Ointment is suitable for very dry skin conditions. It provides a layer of oil to prevent water loss, helping to heal dryness and scaling.

Neriderm Cream is suitable for weeping skin conditions. It allows secretions from the skin to drain away. Neriderm Cream is also suitable for moist, exposed and hairy skin areas.

The use of Neriderm Cream or Neriderm Ointment will be determined by the doctor.

2. Before using the medicine

Do not use the medicine if:

- You are hypersensitive (**allergic**) to the active ingredient diflucortolone valerate or to any of the additional ingredients this medicine contains (see section 6).

- You suffer from rosacea (an **inflammatory skin disease** causing facial redness).
- You suffer from an **inflammation** around the **mouth** (a perioral dermatitis).
- You suffer from an **eye** disease.
- You have **acne**.
- You suffer from a problem in the **genital or anal area** (unless the treatment has been recommended by your doctor).
- You suffer from a **viral skin disease** such as cold sores, herpes, shingles or chickenpox.
- You have a skin **reaction after vaccination** in the treated area.
- You have an untreated **bacterial or fungal** infection.
- You are **pregnant**.
- You are **breast-feeding** and have a skin problem on the breast.

Refer to the doctor if you think that any of the aforementioned conditions apply to you.

Neriderm is not intended for children under 1 year of age and for treating **diaper rash**.

Special warnings regarding the use of the medicine

Before treatment with Neriderm Cream or Ointment, tell the doctor if:

- You have a skin irritation in the lower legs related to circulatory problems called **stasis dermatitis** or **legs ulcers**, as you may have an increased risk of allergic reaction to Neriderm.
- **A new infection develops during the course of treatment with this medicine**, as your doctor may also prescribe for you a medicine to treat the new infection.
- You suffer from **psoriasis**, as the treatment with Neriderm may worsen some types of psoriasis.
- You have a **skin infection**, as this may worsen.
- You suffer from **glaucoma** – high intraocular pressure which may cause loss of vision.

Do not apply a larger amount of Neriderm or use it for a longer period than recommended by the doctor.

The medicine **must not** come into contact with the eyes. In case of contact with the eyes, rinse with cold water.

Children and toddlers

Do not use Neriderm in children under 1 year of age.

Avoid long term continuous use of this medicine. Neriderm may reduce the adrenal gland activity and thus cause a decrease in resistance to diseases. Similar effects may appear in a baby after extensive use of Neriderm by its mother during the last weeks of pregnancy or while breast-feeding.

Dressing the treated area

If the doctor has recommended that the affected areas of your skin treated with Neriderm, be covered with a dressing follow his instructions on how often the dressings need to be changed and the amount of Neriderm in each application. Generally, do not leave any dressing for more than 24 hours. In certain cases, the doctor will recommend changing the dressings every 12 hours. Do not leave the dressings for longer than the recommended time. Check the skin carefully when you change the dressing. If your skin looks more inflamed than before or if any pimples containing pus have appeared, stop using the dressing and refer to the doctor as soon as possible.

Drug interactions

If you are taking, or have recently taken other medicines, including non-prescription medicines or nutritional supplements, tell the doctor or pharmacist.

Neriderm has not been shown to interact negatively with other medicines.

Pregnancy and breast-feeding

Pregnancy: Even at the usual dose, the possibility of a very small risk to the development of the baby in pregnant women treated with Neriderm cannot be ruled out.

Therefore, this medicine should not be used if you are pregnant, trying to become pregnant, or are breast-feeding, unless the treatment is considered essential by your doctor.

Breast-feeding: If you are breast-feeding, Neriderm should not be applied to the breasts.

Driving and use of machinery

It has not been shown that Neriderm has any effect on the ability to drive or use machinery.

Important information about some of the ingredients of the medicine

Neriderm Cream contains stearyl alcohol that may cause local skin reactions (such as contact dermatitis) and also contains parabens that may cause allergic reactions (delayed reactions are possible).

3. How should the medicine be used?

Always use the medicine according to the doctor's instructions. Wash your hands before and after using Neriderm.

Gently apply a **thin layer** of Neriderm onto the affected area of your skin. **Do not use** larger amounts or apply more frequently than recommended by the doctor.

Check with the doctor or pharmacist if you are not sure of the dosage and treatment regimen with the medicine.

The dosage and treatment regimen will be determined by the doctor only. The usual recommended dosage is:

Adults:

The usual recommended dosage: Apply a thin layer onto the affected area twice daily. When your condition improves the doctor may instruct to use once daily. Do not use Neriderm for more than 4 weeks unless the doctor tells you to. If applying to the face do not use Neriderm for more than 5 days and do not dress or cover the area.

Children over 5 years of age and adolescents:

The usual recommended dosage: Apply a thin layer to the affected area twice daily. When your condition improves the doctor may instruct to use once daily. Use Neriderm carefully and not for more than 1-2 weeks.

If applying to the face do not use Neriderm for more than 5 days and do not dress or cover the area.

Children 1-4 years of age:

The usual recommended dosage: Apply a thin layer to the affected area twice daily. Use Neriderm very carefully for short periods of time and generally only on the advice of a dermatologist. Do not use Neriderm for more than 5 days. Do not use dressings to cover the affected area during the treatment.

Do not exceed the recommended dose.

For external use only. Do not swallow.

If you have accidentally applied a higher dosage, if you took an overdose or if a child or someone else has accidentally swallowed the medicine, refer immediately to a doctor or to a hospital emergency room and bring the package of the medicine with you.

If you forgot to apply the medicine at the designated time, do not apply a larger amount to make up for the forgotten time. When you remember, apply the next dose as prescribed for you, and continue with the treatment schedule.

Adhere to treatment regimen as recommended by the doctor. Even if there is an improvement in your health, do not stop treatment with the medicine without consulting the doctor or pharmacist.

Do not take medicines in the dark! Check the label and the dose each time you take the

medicine. Wear glasses if you need them.

If you have further questions regarding use of the medicine, consult the doctor or pharmacist.

4. Side effects

As with any medicine, the use of Neriderm may cause side effects in some users. Do not be alarmed while reading the list of side effects. You might not suffer from any of them.

Rarely an **allergic reaction** to Neriderm may occur. If you feel you are experiencing an allergic reaction, **stop using this medicine and refer to the doctor immediately.**

Sometimes after using Neriderm, you may feel a burning, itching, or irritation of the skin. Your skin may also be reddish or flushed.

Refer to the doctor as soon as possible if you experience the following symptoms while using Neriderm:

- The skin in the treated area or around it becomes thin.
- Acne-like sores.
- Stretch marks.
- Inflammation of the skin around the mouth (dermatitis in the area of the mouth).
- Grouping of small blood vessels becoming prominent under the skin (telangiectasia).
- Increased hair growth (excessive hair growth - hypertrichosis).
- Glaucoma (high intraocular pressure).

The likelihood of the appearance of side effects increases when the treatment with Neriderm is done on large areas (10% and more) of the surface of the body and used for long periods of time (more than four weeks), especially if waterproof dressings are used. The risk of glaucoma increases if Neriderm is used on the skin around the eye.

Very rarely Neriderm can cause side effects such as a decrease in production of the natural hormones by the adrenal gland, which can lead to a disease such as Cushing's syndrome (hypercorticism).

If a side effect occurs, if any of the side effects worsens, or if you suffer from a side effect not mentioned in this leaflet, consult the doctor.

Reporting side effects

Side effects can be reported to the Ministry of Health via the link "Reporting Side Effects of Drug Treatment" that can be found on the home page of the Ministry of Health website (www.health.gov.il) directing to the online form of adverse events reporting or via the following link:

<https://sideeffects.health.gov.il>
Additionally, side effects can be reported to Padagis via the following address: Padagis.co.il

5. How to store the medicine?

• Avoid poisoning! This medicine and all other medicines must be stored in a closed place out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.

• Do not use the medicine after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month.

• Store in a cool place below 25°C.

• After the first opening of the tube, Neriderm can be used for 3 months, but not later than the expiry date.

6. Additional information

• **In addition to the active ingredient, Neriderm also contains:**

Neriderm Cream:

Purified Water, Vaseline White, Paraffin Liquid Heavy, Stearyl Alcohol, Polyoxyl 40 Stearate, Carbopol 980, Edetate Disodium Dihydrate, Methyl Parahydroxy Benzoate, Sodium Hydroxide, Propyl Parahydroxy Benzoate.

Neriderm Ointment:

Vaseline white, Purified Water, Paraffin Liquid Heavy, Dehydymuls® E, Bees wax.

• **What Neriderm looks like and contents of the package:**

Neriderm Cream is an opaque off-white cream.

Neriderm Ointment is an opaque white to white-yellowish ointment. Neriderm Cream and Ointment are packed in an aluminum tube that contains 30 grams.

Manufacturer and registration holder:

Padagis Israel Pharmaceuticals Ltd., 1 Rakefet St., Shoham.

• Revised in March 2023 according to MOH guidelines.

• **Drug registration numbers at the national medicines registry of the Ministry of Health:**

Neriderm Cream: 6150.24636
Neriderm Ointment: 6151.24637

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