

PACKAGE LEAFLET: INFORMATION FOR THE USER

SINODERM N

(0.25 mg + 3.30 mg) / g ointment

FLUOCINOLONE ACETONIDE, NEOMYCIN

• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • Read all of this leaflet carefully before you start taking 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 •

What is in this leaflet?

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

1. WHAT SINODERM N IS AND WHAT IT IS USED FOR

SINODERM N (0.25 mg + 3.30 mg) / g ointment

1 g of ointment contains: 0.25 mg of fluocinolone acetonide and 3.30 mg of neomycin (as neomycin sulfate)

Sinoderm N is a combined preparation comprising two active ingredients, fluocinolone acetonide, and neomycin sulfate.

Fluocinolone acetonide is a synthetic anti-inflammatory corticosteroid, for topical administration for treating inflammatory, allergic and pruritic skin disorders. Fluocinolone acetonide eliminates the symptoms and signs of inflammation at the application site.

Neomycin sulfate is an antibiotic from the group of aminoglycosides, a broad spectrum of action for local use. It acts bactericidally against gram-negative bacteria and staphylococci.

Sinoderm N ointment is designed for local treatment of inflammatory, infected skin diseases.

Sinoderm N ointment reduces the activity of substances in the body that cause inflammation and so reduce the redness, itching and swelling.

It is used to treat the following diseases: eczema in children and adults, infected dermatitis and psoriasis.

Sinoderm N ointment is suitable in dry skin changes.

The medicine is used in adults and children older than one year.

2. BEFORE YOU TAKE SINODERM N

Do not take SINODERM N

Do not use Sinoderm N ointment if you are allergic to fluocinolone acetonide, neomycin sulfate or any of the other ingredients.

Before using Sinoderm N ointment, tell your doctor if you have had an allergic reaction to any medicine that has been used to treat skin changes.

Also tell your doctor if you have diabetes, a chronic disease or a metabolic disorder. Steroids for topical administration may be resorbed through the skin and increase the blood glucose and urine.

The medicine Sinoderm N ointment may affect fetal development.

Tell your doctor if you are pregnant or planning to become pregnant. It is not known whether Sinoderm N ointment passes into breast milk and whether it affects the newborn. Do not use Sinoderm N ointment before you tell your doctor that you are breastfeeding.

Do not use medicine in children without consulting a doctor. Children resorb large amounts of steroids through the skin. Absorption of steroids in children can cause side effects or influence the growth and development if used over a longer period at the higher doses. If you notice a disruption in the growth and development of the child who is on long-term medication therapy with Sinoderm N ointment, be sure to contact your doctor.

If Sinoderm N ointment is used on a large surface, damaged skin or under occlusion, in the long term can lead to absorption in the body. This increases the risk of side effects such as thinning of skin or reduced secretion of adrenal hormones.

If medicine comes into contact with the eyes or other parts of the body such as the mouth, nasal mucous membranes, rinse immediately with cold water.

This medicine should not be used longer than 5 days in the treatment of children or facial skin.

If on the advice of a doctor you cover the affected area, the skin must be well washed before applying a new dose.

If Sinoderm N ointment used to treat lesions on the face or in children, do not use hermetic bandages and diapers to cover the treated areas, because it can increase the absorption of the medicine in the body and increase the risk of side effects.

Do not take medicine Sinoderm N ointment if:

- You are allergic to the medicine or any of the excipients in medicine,
- You have acne,
- Chronic inflammation of the facial skin (acne rosacea)
- Viral infection of the skin (chickenpox, herpes zoster, herpes simplex)
- A bacterial skin infection such as impetigo,
- Fungal skin infection (candidiasis, tinea, athlete's foot),
- An allergy to iodine,
- Inflammatory rash around the mouth, perioral dermatitis,
- Perianal and genital pruritus (severe itching in the genital area and the anus)
- To treat outer ear canal, if you have a perforated membrane of the ear,
- Diaper rash,
- Skin sores due to syphilis,
- Skin sores due to tuberculosis,
- Extended psoriasis with plaques,
- Ulcerations of the skin.

The medicine Sinoderm N ointment is not used in children younger than 1 year.

CAUTION in children, the elderly and people with reduced kidney function.

Take special care with SINODERM N

Sinoderm N ointment is used exclusively externally on skin, so that the affected area in a thin layer is smeared and gently rubbed.

Use Sinoderm N ointment only as recommended by your doctor or as recommended by the manufacturer.

Do not use the medication in larger amounts or over a longer period than recommended.

If Sinoderm N ointment comes into contact with the eyes or mucous membranes of the nose or mouth, immediately rinse with cold running water.

Be sure to wash your hands before and after applying grease to the affected area, and if you use Sinoderm N ointment for the treatment of changes on hands also wash your hands before applying a new dose of the medicine.

Steroids for topical application can be resorbed through the skin and cause side effects in the body in case of long-term use on large areas of skin, in high doses, especially under occlusion or on skin that has been damaged. This increases the risk of local adverse reactions such as thinning of skin of the affected area or whole body, reduced secretion of adrenal hormones. For this reason, continuous, long-term use of this medicine should be avoided whenever possible, especially in children and on large areas of skin.

Medicine Sinoderm N ointment, a corticosteroid with neomycin, may mask clinical signs of bacterial, fungal or viral infection or allergic reactions can hide to antibiotic or other ingredients. One can also experience superinfection with microorganisms insensitive to neomycin sulfate.

Following significant systemic absorption, aminoglycosides such as neomycin sulfate, can lead to permanent hearing loss (ototoxicity) and toxic to kidney damage (nephrotoxicity).

If there is no improvement of symptoms after two to four weeks, contact your doctor.

If recommended by the doctor to cover the affected area treated with this medicine, you should wash your skin before applying a new dose of the medicine and change the bandage.

Plastic bandages are sometimes recommended for the treatment of psoriasis. Sometimes it can lead to the enlargement of changes, worsening of the disease and excessive systemic absorption.

Patients with poor circulation should not use this medicine because it can lead to ulceration of the skin.

If you use medication Sinoderm N ointment for the treatment of changes on facial skin, do not use the medicine for more than 5 days.

Follow the instructions of your doctor.

If you use Sinoderm N ointment in children, do not use plastic diapers or tight clothes and do not use this medicine for more than 5 days.

Covering the skin that is treated with Sinoderm N ointment, can increase the absorption of the medicine that can cause side effects of the medicine especially in children.

Not recommended use of the medicine Sinoderm N ointment in children younger than one year.

Do not use the medicine Sinoderm N ointment in children without the advice of a doctor. Children have an affinity of increased absorption of steroids through the skin so systemic side effects may occur more frequently.

Absorption of steroids in children younger than 2 years is higher and therefore can lead to suppression of the hypothalamic-pituitary-adrenal axis and Cushing's syndrome.

Children must be controlled by a doctor once a week.

Tell your doctor if you notice or think your child is lagging behind in development, and is using this medicine for a long time.

Contact your doctor if your condition is not improving or if you develop signs of a skin infection.

CAUTION in children, the elderly and persons with reduced renal function.

Taking other medicines

Please tell your doctor if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

It is not expected that the medications that you are drinking or get by injection may impact the effect of locally applied Sinoderm N ointment, but some medicines can interact with one another.

If there is significant systemic absorption, neomycin sulfate can intensify and prolong the effects of muscle relaxants on breathing.

Medicines such as furosemide, vancomycin or ethacrynic acid increase the toxic effects of neomycin sulfate on kidneys.

Tell your doctor if you are taking any medicine including medicines obtained without a prescription, such as vitamins, minerals, medicines based on herbs, homeopathic remedies or medicines prescribed by other doctors.

Do not start with the use of this product before you notify your doctor.

Pregnancy and breastfeeding

Ask your doctor or pharmacist for advice before using any medicine.

It is not recommended to use Sinoderm N ointment during pregnancy and lactation, if not necessary, which shall be assessed by your doctor.

If your doctor recommends medicine Sinoderm N ointment, do not lubricate a large area of the skin, do not cover the affected area and do not use this medicine for a long time.

If your doctor has prescribed medicine Sinoderm N ointment for the treatment of changes in your breasts, wash them thoroughly before breastfeeding and before re-applying the ointment.

Medicine Sinoderm N ointment contains propylene glycol and therefore can cause skin irritation.

3. HOW TO USE SINODERM N

Always use SINODERM N exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Cutaneous use only.

Typically, 1-2 times per day apply to the affected area.

Medicine administration usually takes 1-4 weeks.

Medicine should not be used for longer than seven days without a doctor's supervision.

In the treatment of children should be especially careful and use the lowest possible dose that provides a clinical effect.

Before and after applying the medication, wash your hands, unless you are using medicine for the treatment of changes on hands, and then wash your hands thoroughly before re-lubricating.

If you use more SINODERM N than you should

Immediately contact your doctor if you have taken a larger amount of medicine.

It is not expected that a larger quantity of medicine Sinoderm N ointment, cause life-threatening symptoms.

Moreover, long-term use of high doses of steroids can cause symptoms such as thinning of the skin's surface, increased hair growth, acne, stretch marks, itching, reduced skin elasticity and increased susceptibility to mechanical injury, dilated capillaries in the skin or symptoms of systemic absorption when used for a long time, in large quantities, under a bandage or on the damaged skin (irregular distribution of body fat especially around the neck and face, menstrual problems, impotence and loss of or diminished enthusiasm for sex).

If you forget to take SINODERM N

If you forgot to apply SINODERM N ointment do it as soon as possible and then continue as usual. Do not apply double dose to make up for a forgotten dose.

Talk to your doctor or pharmacist if you have any additional questions.

4. POSSIBLE SIDE EFFECTS

Like all medicines, SINODERM N can cause side effects, although not everybody gets them.

Immediately discontinue use of the medicine and contact your doctor if you experience the following signs of an allergic reaction:

- Fainting,
- Difficulty breathing,
- Swelling of the face, lips, tongue or neck.

Stop taking the medicine and contact your doctor if you irritation occurs in the place where you applied Sinoderm N ointment or if you notice signs that are a result of increased absorption of the medicine through the skin, such as:

- Interference with vision (blurred vision unclear) or light aura,
- Mood swings,
- Difficulty sleeping (insomnia)
- Increase body weight, puffiness of the face or
- Muscle weakness and feeling tired.

During the administration of the medicine Sinoderm N ointment you may experience side effects at the injection site:

- Irritation at the site of application such as redness, burning sensation or itching,
- Allergic skin inflammation (contact dermatitis)
- Thinning of the skin's surface,
- Changes in skin color, increased hair growth, acne,
- Changes in skin elasticity (stretch)
- Expansion of the skin capillaries
- Increased sensitivity to mechanical injury.

Rarely, and that when the composition is applied to a large area of skin over a longer period, with occlusion and / or in children, there may be systemic side effects with signs of lowering the function of the adrenal cortex, impaired hearing (ototoxicity), impaired renal function.

In the case of these and possibly other symptoms that could be an adverse reaction to medicine Sinoderm N ointment, but are not mentioned in this leaflet, please tell your doctor or pharmacist.

In the case of side effects the therapy should be stopped immediately.

It is not known whether medicine Sinoderm N ointment affects fertility.

Reporting of suspected 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.

5. HOW TO STORE SINODERM N

Keep out of the reach and sight of children.

Throw the opened tube four weeks after opening to prevent infection. Write down the date when you opened the tube.

Store below 25 °C.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

The shelf life of medicine is 2 years from the date of manufacture indicated on the packaging of the medicine.

6. FURTHER INFORMATION

What SINODERM N contains

Active substance: 1 g of ointment contains: 0.25 mg of fluocinolone acetonide and 3.30 mg of neomycin (as neomycin sulfate)

Other ingredients: propylene glycol; Sorbitan oleate 80; paraffin, liquid, light paraffin, white soft.

What SINODERM N looks like and contents of the pack

The appearance: homogeneous, almost white to pale yellow semitransparent ointment.

Packaging: tube with 15 g of ointment.

Regime of dispensing

The medicine is issued on prescription.

Manufacturer

Galenika ad, Batajnički drum bb, Belgrade, Serbia