

PACKAGE LEAFLET: Information for the user

SODERM PLUS

Ointment – (0.5 mg + 30 mg) / g

(Betamethasone dipropionate, Salicylic acid)

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 symptoms are the same as yours.
- If you notice any side effects, tell your doctor or pharmacist. This applies also for side effects not listed in this leaflet. See section 4.

In this leaflet:

1. What Soderm Plus is and what it is used for
2. What you need to know before you use Soderm Plus
3. How to use Soderm Plus
4. Possible side effects
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6. Content of the pack and further information

1. WHAT SODERM PLUS IS AND WHAT IT IS USED FOR

Soderm Plus contains a combination of the active substances betamethasone dipropionate (corticoid) and salicylic acid (keratolytic, antiseptic).

Soderm Plus is used in:

- chronic dry skin diseases (dermatoses);
- psoriasis;
- chronic eczema or allergic skin inflammations (e.g. professional eczema);
- seborrhoic eczema of the head;
- exfoliative keratolysis (dyshidrosis lamellosa sicca);
- symmetrically localized chronic eczema;

- lichen ruber planus;
- ichthyosis.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE SODERM PLUS

Soderm Plus should not be used:

- in case of hypersensitivity to betamethasone, salicylic acid, other salicylates or to any of the excipients mentioned in section 6;
- in virus-related diseases and tuberculosis of the skin;
- in bacterial diseases of the skin, e.g. erysipelas or syphilitic skin manifestations;
- in fungal infections of the skin (dermatomycoses);
- in chickenpox (varicella);
- for vaccination reactions;
- in rosacea.

Warnings and precautions

Talk to your doctor or pharmacist before using Soderm Plus.

Soderm Plus should be used with caution on the face, but never in the eye area.

Because of the content of salicylic acid, long-term treatment (longer than 4 weeks) and / or application on large skin areas (over 10% body surface) must not be performed. This is especially true for infants, toddlers and patients with renal impairment. In the presence of an infection, addition of a therapy with antibiotics should be discussed.

In case when a large skin area is treated (over 10% body surface), when used under occlusive dressing or long-term treatment (longer than 4 weeks), absorption of the active substances may be observed.

In such cases, precautions of therapy with corticosteroids and salicylic acid should be taken in consideration. It should not be applied more than 50 g Soderm Plus in a week.

Other precautions:

In case of treatment in the genital or anal area, because of the excipients white soft paraffin and light liquid paraffin, during concomitant use of latex condoms, it can lead to an impairment of the safety of condoms.

Children

Because of the content of salicylic acid, long-term treatment (longer than 4 weeks) and / or application on large skin areas (over 10% body surface) must not be performed in infants and toddlers.

Using Soderm Plus with other drugs

Please tell your doctor or pharmacist if you are taking / using, have recently taken / used or plan to take / use other drugs.

Salicylic acid, which is an active ingredient of Soderm Plus ointment, may increase the absorption of other drugs applied in the same area of the skin.

In case of long-term application in a large area, the absorbed salicylic acid may:

- lead to an increased concentration of concurrent methotrexate, and thus enhance its toxic effect;
- enhance the blood sugar-reducing effect of sulfonylureas.

Pregnancy and breastfeeding

Consult with your doctor or pharmacist before using this drug if you are pregnant or breastfeeding, if you think that you are pregnant or if you are planning a pregnancy.

Salicylic acid can be absorbed to a considerable extent via the skin. For this reason, Soderm Plus should not be used during pregnancy.

During breastfeeding, it should not be used in the chest area, otherwise only after a strict risk-benefit assessment.

Driving and using machines

There are no data available regarding the ability to drive and use machines.

3. HOW TO USE SODERM PLUS

Always use Soderm Plus after talking to your doctor. Consult with your doctor or pharmacist if you are not sure.

Unless otherwise prescribed by the doctor, the usual dose is:

Soderm Plus is applied twice daily, morning and evening, to the affected skin areas. The once-daily application of Soderm Plus is sufficient for mild discomfort or after improvement.

Method of administration

For cutaneous use.

The duration of treatment

The doctor decides on the duration of treatment. It depends on the type, severity and course of the disease. Because of possibly increased absorption, the duration of the application should not exceed 4 weeks.

Talk to your doctor or pharmacist if you have the impression that the effect of Soderm Plus is too strong or too weak.

If you use more Soderm Plus than you should

If a large amount of the ointment is applied on the skin, or all the content of the tube in a short time, toxic symptoms are not expected. However, as a counteraction, the ointment should be washed out of the skin or wiped away with a soft clothing.

Because of increased absorption of salicylic acid (for example under occlusive dressing or long-term treatment), the following symptoms may appear: nausea, vomiting, irritability, tinnitus, hearing loss, epistaxis, and dryness of the mucous membranes. Similar side effects will appear if Soderm Plus is taken accidentally.

If you use Soderm Plus in a large amount or if you take this drug accidentally, inform your doctor and he will tell you about the treatment of overdose.

Take the tube or the box with you in order that the doctor knows about the active substance that is taken.

If you forget to use Soderm Plus

Please keep the medical prescription. If you forget to use one dose or if in one application you have used less ointment than you should, skip those applications and continue the treatment according to the medical prescription. Do not use double doses or higher doses to make up the forgotten ones.

If you stop using Soderm Plus

The regular use is important for the treatment success. Consult with your doctor before stopping the treatment with Soderm Plus by your own decision because of for example: side effects appearance or because of improvement feeling. Every dose change or treatment stop should be done only with medical recommendation.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine also can cause side effects, although not everybody gets them. For the evaluation of the undesirable effects the following frequency indicators will be used:

Very common	more than 1 patient in 10
Common	up to 1 patient of 10
Uncommon	up to 1 patient of 100
Rare	up to 1 patient of 1,000
Very rare	up to 1 patient of 10,000
Not known	cannot be estimated from the available data

If the product causes side effects such as: skin thinning (skin atrophy), striae cutis, blister formation (miliaria), acne, white staining of the skin (hypopigmentation) and enlargement and multiplication of skin vessels (telangiectasia), the product should be discontinued and a doctor should be consulted. The same thing is to be done if skin burning, itching, dryness of the skin, folliculitis and altered hair growth occur.

Under occlusive dressings, the aforementioned effects may occur more quickly. In addition, skin softening and secondary infections can only be caused by covering dressings.

Long-term use of salicylic acid can lead to dry skin, skin irritation and undesirable scaling. Hypersensitivity reactions occur occasionally, rarely contact allergies.

In these cases, Soderm Plus should be discontinued and a doctor should be consulted.

If you notice side effects, tell your doctor or pharmacist. This applies also for side effects not mentioned in this leaflet.

5. HOW TO STORE SODERM PLUS

Keep out of the reach and sight of children!

Do not store above 25°C!

Do not use the drug after the expiry date which is stated on the package.

6. CONTENT OF THE PACK AND FURTHER INFORMATION

What Soderm Plus contains:

The active substances are: betamethasone dipropionate and salicylic acid.

1 g ointment contains 0.5 mg betamethasone (as 0.64 mg betamethasone dipropionate) and 30 mg salicylic acid.

The excipients are: white soft paraffin and light liquid paraffin.

Content of the pack

Box with one tube of 30 g.

Marketing Authorisation Holder (MAH) and Manufacturer:

PROFARMA sh.a.,

St. "Skënder Vila",

Tirana, Albania.

Tel.: +355 4 23 89 602

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