PACKAGE LEAFLET: Information for the user

SODERM LOTIO

1,22 mg / g – Emulsion

(Betamethasone valerate)

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

In this leaflet:

1. WHAT SODERM LOTIO IS AND WHAT IT IS USED FOR?

Soderm Lotio contains a hormone of the adrenal cortex (glucocorticoid).
Betamethasone is a synthetic glucocorticoid, which like the natural hormone of the adrenal cortex, cortisol, has an anti-inflammatory (antiphlogistic) and anti-allergic (immunosuppressive) effect when applied locally (on the skin).
Soderm Lotio is used for the treatment of the inflammatory, allergic or itching skin diseases in which the symptomatic use of potent topical corticosteroids is indicated.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE SODERM LOTIO?

Soderm Lotio should not be used:

- in case of hypersensitivity to betamethasone, methyl-4-hydroxybenzoate or any of the excipients listed in section 6

- in specific skin processes (skin tuberculosis, syphilis), rosacea (anti-inflammatory disease of the skin, with pustules, in the face), rosacea-like (perioral) dermatitis (anti-inflammatory skin disease, mainly around the mouth), acne, itching (pruritis) without inflammation, virus-related skin diseases (e.g. herpes simplex, zoster, varicella), vaccination reactions, pruritis anogenitalis (itching of the anus and genitals), as well as untreated skin infections, unless the doctor has permitted it
- in prolonged chronic-stationary forms of psoriasis
- in infants under 1 year; inflammatory skin changes, including diaper rash, should not be treated with Soderm Lotio
- on the eyelid and in the eye area. Application on the eyelid and in the eye area should be avoided as this can lead to glaucoma (increased intraocular pressure) and eye lens blurring (cataract). Soderm Lotio should not be used in the eye.

Take special care with Soderm Lotio

Talk to your doctor or pharmacist before using Soderm Lotio.

During the use of Soderm Lotio, special care is required:

- if the facial area is treated; since the skin in the facial area is particularly sensitive, to avoid changes in it, long-term therapy with local corticosteroids should be avoided
- in the presence of a secondary bacterial and / or mycotic skin infection; in this case, an appropriate antimicrobial treatment is required; if the infection continues to spread, external corticoid use should be discontinued and the doctor, who will decide on further treatment should be notified
- in the treatment of psoriasis.

Soderm Lotio can be applied under occlusive dressings only with the doctor’s advice. If you use Soderm Lotio under occlusive dressings, the skin should be cleansed before changing the dressing.

Use of Soderm lotio on the skin around leg wounds can increase the risk for allergic reactions or infections.

If Soderm Lotio is applied in the facial area, it must not come into contact with the eyes or mucous membranes.

Avoid long-term use (more than 3 weeks), high doses (use in a large area), as well as the use under occlusive dressings (dressing that covers without applying pressure). In these cases, it

is not excluded that betamethasone is absorbed in the body through the skin (percutaneous absorption) and cause hormonal disorders.
If blurred vision or other visual disturbances occur, inform your doctor.

Children

Do not use in children under 1 year.
In children, Soderm Lotio should only be used for a short time (less than 1 week) and on a small area (less than 10 % of the body surface). In general, caution should be exercised when treating children, as it may result in increased absorption of the glucocorticoid through the child's skin compared to adults.
In children under 12 years, long-term treatment or use on large area should be avoided as much as possible, because even without occlusive dressings, increased percutaneous absorption and thus an adrenal suppression is possible. It should be remembered that diapers can have the effect of occlusive dressings.

Using other medicines with Soderm Lotio

Inform your doctor or pharmacist if you are taking / using or have recently taken / used or plan to take / use other medicines.
Caution is advised during concomitant use of Soderm Lotio with substances that inhibit the CYP3A4 enzyme system. These substances (e.g. ritonavir, itraconazole) inhibit the corticosteroid metabolism, leading to increased systemic availability. This may increase the risk of side effects.

Pregnancy and breastfeeding

If you are pregnant or breast-feeding, if you think you might be pregnant or you are planning to have a baby, before using this drug, consult your doctor or pharmacist.

Pregnancy

During pregnancy, the use of Soderm Lotio should be avoided as much as possible and, if necessary, should be as short as possible and on an area as small as possible. Since prolonged treatment with glucocorticosteroids during pregnancy can not exclude growth retardation and fetus damage, talk to your doctor if you want to become pregnant, if you are already pregnant or think you are pregnant. The doctor will decide whether to use Soderm Lotio during pregnancy.

Breastfeeding
Betamethasone passes into breast-milk. A damage to the infant is not yet known. Nevertheless, the indication of this medicine in the breast-feeding period should be striclty provided. Consult your doctor. He will decide for the use of Soderm Lotio during breast-feeding.
Contact of the infant with the treated body parts should be avoided. Do not use Soderm Lotio on the breast area, so that accidental ingestion by the infant is prevented.
If due to the disease, higher doses or a large-area application of more than 20% of the body surface is required, breast-feeding should be discontinued.

Driving and using machines
There is no experience regarding the impairment of driving performance or the ability to operate machinery.

Important information about some of the excipients of Soderm Lotio
Cetostearyl alcohol can cause local skin reactions (e.g. contact dermatitis).

During use in the genital or anal area, because of the excipient liquid paraffin, simultaneous use of condoms made of latex can lead to a reduction of its tensile strength and thus compromise the safety of condoms.

3. HOW TO USE SODERM LOTIO?
Always use this medicine exactly as your doctor has told you. Ask your doctor or pharmacist if you are not sure.

If not otherwise prescribed, the usual dose is:
At the beginning of the treatment, Soderm Lotio should be applied thinly to the affected skin areas 1 – 2 times daily. When improvement occurs, you should use Soderm lotio less frequently: one application per day is sufficient.
In children older than 1 year, one application per day is usually sufficient.

Method of administration
Soderm Lotio is applied thinly to the affected skin and gently massaged if possible.

Because Soderm Lotio is flammable, during and immediately after use, you should avoid open flames and heat (including hair dryer use) and you should not smoke.

Duration of administration

For adults, the treatment should not last longer than 3 weeks. Long-term treatment (longer than 3 weeks) or large area use (more than 20% of the body surface) should be avoided.
The use in children should be carried out over the shortest possible period of treatment at the lowest possible dose, which still ensures efficacy. Treatment in children should not last longer than 1 week and should be carried in small areas (less than 10% of body surface). Long-term treatment should be prescribed by the doctor.

If you use more Soderm Lotio than you should

You can continue treatment with the prescribed doses. From the short-term overdose no side effects are expected.

The occurrence of acute overdose symptoms is unlikely. After chronic overdose or abuse, a clinical picture of hypercortisolism (increased production of cortisone) may develop. In this case, under medical supervision, the dosage of Soderm Lotio should be gradually reduced due to the potential risk of adrenal insufficiency, by reducing the frequency of use or substitution with a less potent corticosteroid.

If you forget to use Soderm Lotio

Do not use a double dose if you missed the previous dose.

If you stop using Soderm Lotio

You can put at risk the success of treatment. Talk to your doctor or pharmacist before discontinuing the treatment with Soderm Lotio.
If you have any further questions on the use of this drug, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Soderm Lotio may cause side effects, although not everybody gets them. The following list includes all known side effects under treatment with the active substance betamethasone valerate, including those under high dose or long-term therapy.

For the evaluation of side effects, the following frequency indicators are used:

Very common	More than 1 patient in 10
Common	up to 1 in 10 patients
Uncommon	up to 1 in 100 patients
Rare	up to 1 in 1.000 patients
Very rare	less than 1 patient in 10.000
Not known	Frequency cannot be estimated from the available data

Possible side effects

The following side effects have been observed so far:

Infections and infestations

Very rare: opportunistic infections (infections favoured by a weakening of the immune system).

Immune system disorders

Very rare: local hypersensitivity reactions.

If signs of hypersensitivity occur, the use should be discontinued and the doctor should be contacted.

Local hypersensitivity reactions may be similar to the symptoms caused by the disease.

Endocrine disorders

Very rare: suppression of adrenal cortex function:

Cushingoid phenomena (e.g. moonface, trunk adiposity), delayed weight gain / growth retardation in children, reduction of bone density, increased intraocular pressure (glaucoma), increased blood sugar / urinary glucose levels, eye lens blurring (cataract), high blood pressure, overweight / obesity, decreased endogenous cortisol levels, alopecia, trichorrhexis.

The prolonged or extensive use of corticosteroids may result in systemic absorption of the active substance, therefore the risk of systemic side effects mentioned above during the use of Soderm Lotio may not be excluded. The occurrence of systemic effects is more likely in infants and children and when used under occlusive dressings. In infants, diapers can act like occlusive dressings. After using topical glucocorticoids, children may be more sensitive to systemic absorption of the drug than adults.

Eye disorders
Not known: blurred vision.

Skin and subcutaneous tissue disorders
Common: pruritus, local burning of the skin / local pain of the skin.
In some cases, even with recommended doses, allergic skin reactions occur.

Very rare: allergic contact dermatitis / dermatitis (including rosacea-like [perioral] dermatitis, inflammatory skin disease, mainly around the mouth), redness of the skin (erythema), rash, urticaria, pustular psoriasis, thinning of the skin / skin atrophy, skin wrinkles, skin dryness, striae, telangiectasia (enlargement and proliferation of small superficial skin vessels), skin pigmentation change, hypertrichosis (increased hair growth), exacerbation of the underlying symptoms.
Not known: steroid acne.

Prolonged (over 3 weeks) use or use in a large area, especially under occlusive dressings or in skin folds, may cause changes in the treated skin area, such as thinning of the skin, striae, steroid acne, telangiectasia, change in skin pigmentation, hypertrichosis.
Application of glucocorticoid-containing topicals like Soderm Lotio to wounds, can interfere with wound healing.

General disorders and administration site conditions
Very rare: irritation / pain at the site of application.

Methyl 4-hydroxybenzoate can cause hypersensitivity reactions, including delayed reactions.

Special instructions

If side effects occur, stop using Soderm Lotio and consult your doctor.

If any of the mentioned side effects gets serious or if you notice any side effect not mentioned in this leaflet, inform your doctor or pharmacist.

5. HOW TO STORE SODERM LOTIO?

Keep out of the reach and sight of children!

Do not store above 30 ºC.

Close the bottle tightly after use.

The drug is flammable. Protect from fire, flames, heat and direct sunlight.

Do not use this medicine after expiry date marked in the box and label.

6. FURTHER INFORMATION

What Soderm Lotio contains

The **active substance** is betamethasone valerate.

1 g emulsion contains 1.22 mg betamethasone valerate (equivalent to 1 mg betamethasone).

The **excipients** are: methyl-4-hydroxybenzoate, macrogol cetostearyl ether (20 - 22), cetostearyl alcohol, digolilstearate, liquid paraffin, glycerol 85%, 2-propanol, citric acid monohydrate, purified water.

What Soderm Lotio looks like and content of the pack

Soderm Lotio is a white emulsion for use in the skin, packaged in a box with a plastic bottle of 20 ml.

Marketing Authorisation Holder (MAH) and Manufacturer:

PROFARMA sh.a.,

St. “Skënder Vila”,

Tirana, Albania.

Tel.: +355 4 23 89 602

This package leaflet was last revised in November 2023.