PACKAGE LEAFLET: Information for the user

KARISON

Cream – 0.5 mg/g

Ointment – 0.5 mg/g

(Clobetasol propionate)

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 these side effects gets worse, or if you notice side effects not mentioned in this leaflet, inform your doctor or pharmacist.

In this leaflet:

1. WHAT KARISON IS AND WHAT IT IS USED FOR?

Karison cream and ointment contain the active substance clobetasol propionate which is a steroid for topical use.

Karison is used for the treatment of localized plaques of inflammatory skin diseases, resistant to therapy, in which the symptomatic use of topical glucocorticoids with a very strong effect is indicated, e.g. in psoriasis.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE KARISON?

Do not use Karison:

Karison should not be used in any case on the following conditions and diseases:

- in hypersensitivity to clobetasol propionate, methyl 4-hydroxybenzoate (paraben, present only in Karison cream), stearyl alcohol (present only in Karison ointment), or to any of the other ingredients of the medicinal products
- in inflammatory facial skin symptoms (rosacea), extensive forms of chronic stationary psoriasis, acne vulgaris, inflammatory perioral skin symptoms [rosacea-like (perioral) dermatitis], pruritus without inflammation, pruritus anogenitalis, viral infections of the skin (e.g. herpes simplex, varicella), skin-specific processes (tuberculosis of the skin, syphilis), vaccine reactions, and also in untreated skin infections (bacterial, fungal, or parasitic)
- in infants, toddlers and children under 3 years (including treatment of inflammatory skin changes, e.g. nappy rashes)
- in the eyes, eyelids and the periorbital region, as this may lead to glaucoma or cataracts. This medicine is not for use in the eye.

Karison should not be used on the face (see “Take special care with Karison”).

Take special care with Karison

Please, talk to your doctor or pharmacist before using Karison:

- in the skin of the face and neck, also in skin wrinkles (intertriginous, such as axillary and genital / anal area), except sclerotic and atrophic genital lupus, because the skin may become thinner (atrophic changes) when potent glucocorticoids are applied; also in erosive, moist areas of the skin, cracks or in fissures and ulcerations
- in skin infections, an appropriate antimicrobial therapy must be initiated if an inflammatory skin lesion is developing an infection; any spread of infection requires discontinuation of topical glucocorticoid therapy
- when treating psoriasis, as there may be cases of rebound phenomenon, and due to skin barrier function impairment, the active ingredient may be highly absorbed
- with occlusive dressings; bacterial infections are favored by occlusive, warm, moist conditions; Karison can be used with occlusive dressing only after consulting the doctor; if occlusive dressings are used, the skin should be cleaned when changing dressings

- near the area of leg ulcers because of an increased risk of hypersensitivity reactions and infections
- in patients with liver function disorder
- in patients with diabetogenic metabolism
- if you experience newly developed bone pain or worsening of previous bone symptoms during a treatment with Karison, especially if you have been using Karison for a prolonged time or repeatedly
- if you use other oral / topical medication containing corticosteroids or medication intended to control your immune system (e.g. for autoimmune disease or after a transplantation). Combining Karison with these medicines may result in serious infections.

If symptoms such as blurred vision or other visual disturbances occur, talk to your doctor.

Premature babies, newborns, infants, young children and children

Infants and young children under 3 years of age should not be treated with Karison.
Karison is not recommended in children aged 3 to 12 years. Children in this age group should only be treated in exceptional cases and for a few days.
Continuous long-term use may cause hormonal disbalance due to skin absorption of the active ingredient.

Elderly

Karison should not be used in extended areas.
In long-term and / or repeated use of clobetasol propionate, a careful supervision of the patients is needed, similar to that during oral or parenteral use of corticosteroids.
When treating in the genital or anal area with concomitant use of condoms made of latex, because of the excipients white soft paraffin and light liquid paraffin, it may lead to a reduction in tensile strength and thus impair the safety of condoms.

Taking other medicines

Inform your doctor or pharmacist if you are taking / using, have recently taken / used, or plan to take / use other drugs, including those obtained without a prescription.

Concomitant use with drugs that inhibit the CYP 3A4 enzyme system (e.g. ritonavir, itraconazole) showed an inhibition of the metabolism of corticosteroids, which led to an increased systemic availability. This may increase the manifestation of the adverse effects. Keep in mind that these data apply also in short-term use.
Interactions of clobetasol propionate with other drugs have not been described, but they may be possible e.g. with diuretics, anticoagulants and in inappropriate treatment and absorption conditions, e.g. strongly damaged skin.

Pregnancy and lactation

If you are pregnant or breast-feeding, think you might be pregnant or plan to have a baby, talk to your doctor or pharmacist before using this medicine. During pregnancy, the use of Karison must be avoided as much as possible, and if it is absolutely necessary, it should be used for the shortest possible time and in a limited area.
Long-term treatment with glucocorticoids during pregnancy can lead to intrauterine growth retardation of the child. Inform your doctor if you want to get pregnant, if you are pregnant or might be pregnant. The doctor will then decide on the use of Karison.

Glucocorticoids such as clobetasol are excreted in breast milk.
An impairment of the baby has not yet become known. Nevertheless, the indication during breast-feeding should be strictly specified and clobetasol should only be used during breast-feeding if it is absolutely necessary. Consult your doctor.
The contact of the infant with the treated parts of the skin, should be especially avoided. Karison should not be applied to the breasts to avoid accidental ingestion by the baby.

Driving and using machinery

Karison is not expected to affect the ability to drive or use machines.

Important information about some of the excipients of Karison

<u>Cream</u>

Cetylstearyl alcohol may cause local skin reactions (e.g. contact dermatitis).
Methyl-4-hydroxybenzoate may cause hypersensitivity reactions, may be delayed.

Ointment

Stearyl alcohol may cause local skin reactions (e.g. contact dermatitis).

3. HOW TO USE KARISON?

Always use Karison cream or ointment as your doctor has told you. Talk to your doctor or pharmacist if you are not sure.

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

Karison is applied once daily in a thin layer in the affected areas of the skin. The treated area should not exceed 10% of the body surface. For reasons, it is pointed out that patients should not use more than 50 g of Karison cream or ointment per week.

Karison should be used in children over the shortest possible treatment period with the lowest possible dosage which still ensures effectiveness.

Children, aged 3 to 12 years, should only be treated in exceptional cases and for a few days (see section 2).

Elderly, patients with kidney or liver problems or patients with diabetogenic metabolism, should only be treated for the shortest possible treatment period with the lowest possible dosage which still ensures effectiveness.

Method of administration

For topical use.

Note: Wash your hands after using Karison, unless the hands are the area to be treated.

Duration of use

The duration of treatment is limited to maximum 2 weeks. If there is no improvement after this, you should contact the doctor again.

As soon as the disease is under control, treatment with topical corticosteroids should be gradually discontinued and skin care should continue as a basic therapy. The doctor will decide

this and the continuation of your treatment.

Note: If an infection occurs, the therapy with Karison should be discontinued and you should inform your doctor.
Talk to your doctor or pharmacist if you have the impression that the effect of Karison is too strong or too weak.

If you use more Karison than you should
An acute overdose is unlikely to occur, nevertheless, after chronic overdose or misapplication, the clinical picture of hypercortisolism (high production of cortisol) may occur. In this case, the dose of Karison should be gradually reduced under medical observation, because the risk of adrenal failure exists. This may be achieved by reducing the frequency of use or replacing it with a less potent corticosteroid.

If you forget to use Karison
Do not use a double dose if you forget to use the previous dose.

If you stop using Karison
You may risk the success of the treatment. Talk to your doctor before you discontinue the treatment with Karison.
If you have further questions on the use of this drug, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all drugs, Karison may cause side effects, although not everybody manifests them.
For the evaluation of side effects, the following indicators of frequency are used:

Very common	more than 1 in 10 patients
Common	Up to 1 in 10 patients
Uncommon	Up to 1 in 100 patients
Rare	Up to 1 in 1,000 patients
Very rare	Up to 1 in 10,000 patients
Unknown	The frequency cannot be estimated from the available data.

These side effects are reported from the therapy with clobetasol propionate cream or ointment:

Infections and infestations

Very rare: Opportunistic infection (infection that is favoured from weakened immune system)

Immune system disorders

Very rare: Local hypersensitivity reactions

Local hypersensitivity reactions may appear during treatment and they may resemble the disease symptoms.

If there are symptoms of a hypersensitivity reaction, you should immediately discontinue the use of the drug.

Eye disorders

Not known: Blurred vision

Endocrine disorders

Very rare: suppression of the adrenal glands
cushingoid symptoms (e.g. facies lunata, truncal obesity), delayed weight gain / growth retardation in children, osteoporosis, high ocular pressure (glaucoma), hyperglycaemia / glucosuria, cataracts, high blood pressure, overweight / obesity, reduced endogenous cortisol, alopecia, trichorrhexis.

Long-term use (more than 2 weeks) or the use in large areas (more than 10% of the body surface) of Karison may lead to systemic absorption of the active ingredient, hence the risk of side effects mentioned above is not excluded. The occurrence of systemic side effects is higher in young children and when used under occlusive dressing. In young children, diapers may serve as occlusive dressing (see section 2 “What you need to know before you use Karison?”).

Skin and subcutaneous tissue disorders

Common: pruritus, local skin burning / skin pain

Uncommon: local skin atrophy, striae, dilatation and proliferation of small, superficial, skin blood vessels (teleangiectasia)

Very rare: thinning of the skin, wrinkling of the skin, dryness of the skin, change in skin pigmentation, hypertrichosis, exacerbation of the underlying symptoms, allergic contact dermatitis / dermatitis (including rosacea-like [perioral] dermatitis), pustular psoriasis, erythema, rash, urticaria

Not known: steroidal acne, folliculitis, echymosa, milia formation.

Long-term use (more than 2 weeks) or the use in large areas (more than 10% of the body surface) of potent corticosteroid preparations may cause thinning of the skin, especially when used under occlusive dressings or in skin wrinkles.

General disorders and administration site conditions

Very rare: irritation / pain at the application site

After long - term use in the facial area, atrophic skin changes may occur more frequently than in other body areas.

The treated symptoms may be exacerbated.

Other side effects of the cream

Methyl-4-hydroxybenzoate may cause hypersensitivity reactions, may be delayed.

Special instructions:

If local skin irritations appear, the treatment should be discontinued and appropriate symptomatic treatment should be started.

Inform your doctor or pharmacist if any of the side effects appears to you, or if you notice any side effect not listed in this leaflet.

5. HOW TO STORE KARISON

Keep the drug out of the reach and sight of children.

Do not use the drug after the expiry date which is stated on the package as “Exp.”.

Do not store above 25°C.

6. OTHER INFORMATION

What Karison contains:

The active substance is clobetasol propionate.

1 g cream contains 0.5 mg clobetasol propionate.

The excipients are: methyl-4 hydroxybenzoate, sodium edetate, white paraffin, cetylstearyl alcohol, liquid paraffin, polysorbate 80, sorbitan sesquioleate, glycerol, purified water.

1 g ointment contains 0.5 mg clobetasol propionate.

The excipients are: white paraffin, liquid paraffin, stearyl alcohol, sorbitan sesquioleate, polysorbate 80, sodium edetate, purified water.

Content of the pack

Karison cream: carton box with one tube of 30 g.

Karison ointment: carton 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

This leaflet was last revised in January 2024.