

PACKAGE LEAFLET: Information for the patient

PREDNIZOLON 0.5%

Ointment – 0.005 g / g

(Prednisolone acetate)

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. 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.

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1. WHAT PREDNIZOLON 0.5% IS AND WHAT IT IS USED FOR

Prednisolone acetate is a glucocorticoid that beside systemic use, has also local use. It has anti-inflammatory, hypoallergenic, vasoconstrictor and antiproliferative properties, therefore it is used in inflammatory skin diseases of different origin, since it reduces a few symptoms, e.g. itching.

The skin absorption of prednisolone has a low rate when applied as an ointment. It has a very low impact on several parameters, such as plasma hydrocortisol levels and urinary excretion of 17-ketosteroids and 17-hydroxycorticosteroids.

Prednizolon 0.5% is used in several inflammatory diseases:

- contact dermatitis;
- seborrheic dermatitis;
- atopic dermatitis;
- photodermatitis, psoriasis;
- local neurodermatitis.

2. BEFORE YOU USE PREDNIZOLON 0.5%

Do not use Prednizolon 0.5%:

- if you are hypersensitive (allergic) to glucocorticoids, the same therapeutic group as prednisolone acetate, or to any other excipient, because an allergic reaction may occur, including anaphylaxis;
- in bacterial and viral skin infections;
- in fungal skin diseases;
- in skin tuberculosis;
- in rosacea;
- in acne vulgaris.

If you get any of the above-mentioned conditions, do not use the ointment any longer, contact your doctor and follow the medical advice. If you visit any other doctor or dentist, please inform him you are under Prednizolon 0.5% treatment.

Take special care with Prednizolon 0.5%

Long-lasting treatment, especially on face skin, should be avoided, independently from patient age.

Taking other medicines

Tell your doctor or pharmacist if you are taking/using, or have recently taken/used any other medicines, including medicines obtained without a prescription.

Never forget to inform the doctor that you are under Prednizolon 0.5% ointment treatment if any other medicine is prescribed to you during the same period.

Prednizolon 0.5% may affect their action mode or other medicines can affect the way it acts. You might need a different dosage of this medicine or to take different medicinal products. Your doctor or pharmacist will advise you.

Pregnancy and breastfeeding

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

Driving and using machines

No effects on ability to drive and use machines have been observed in patients treated with this medicine.

Important information about some of the excipients of Prednizolon 0.5%

This ointment contains cetyl alcohol and hydrogenated wool fat, which may cause local skin reactions (e.g. contact dermatitis).

3. HOW TO USE PREDNIZOLON 0.5%

Your doctor will inform you about the frequency and quantity of Prednizolon 0.5% you need to use. Always use this medicine exactly as your doctor has told you, never change the dosage by yourself, independent of how you might feel.

Ask your doctor or pharmacist if you are not sure how to use this medicine.

Apply a thin layer of the ointment on the affected area 2 or 3 times daily.

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

If you use more Prednizolon 0.5%

If you use more Prednizolon 0.5% than you should, or if the children take it by mistake, please contact your doctor or hospital straight away for receiving any advice on the risks or the actions to be taken.

If you forget to use Prednizolon 0.5%

If you forget to use a dose, use the next dose at its usual time.

Do not use a double dose to make up for a forgotten dose.

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, Prednizolon 0.5% can cause side effects, although not everybody manifests them.

The side effects are mostly dose-related and disappear when the dosage is lowered or when the treatment is stopped. Some side effects may be more common at the beginning of the treatment and disappear spontaneously with continued treatment.

During local and long-lasting corticosteroid treatment, you might notice contact dermatitis, skin pigmentation disorders or secondary infections. Mild skin irritation, burning sensation, itching and skin rash are considered rare side effects.

Recently, the elevated risk of central serous chorioretinopathy (disease of the retina with loss of vision) linked to the systematic use of corticosteroids, has also been reported after local administration, including the topical dermal route. If you suffer from blurred vision or other visual disturbances, you should see an ophthalmologist.

Talk to your doctor or pharmacist if you notice any side effects not listed in this leaflet.

5. HOW TO STORE PREDNIZOLON 0.5%

Keep out of the sight and reach of children!

Do not use Prednizolon 0.5% after the expiration date stated on the packaging.

Do not store above 25°C.

6. FURTHER INFORMATION

What Prednizolon 0.5% contains

The active substance is prednisolone acetate.

1 g ointment contains 0.005 g prednisolone acetate.

The other ingredients are: cetyl alcohol, hydrogenated wool fat, soft white paraffin.

Content of the pack

Carton box with 1 lacquered aluminum tube of 5 g.

Marketing Authorisation Holder (MAH) and Manufacturer:

PROFARMA Sh.a,

St. "Skënder Vila",

Tirana, Albania.

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