

PACKAGE LEAFLET: Information for the patient

PREDNIZON

Tablets – 5 mg

(Prednisone acetate)

Read all of this leaflet carefully before you start taking 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 becomes worse or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

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

1. WHAT PREDNIZON IS AND WHAT IT IS USED FOR

Prednisone is a glucocorticoid that inhibits the formation, releasing and activity of endogenous inflammatory mediators, including prostaglandins, kinins, histamine, liposomal enzymes and complement cascade. It also alters the organism immune response. In haematopoietic system it decreases lymphocytes, eosinophils and basophils number, but increases neutrophils, thrombocytes and erythrocytes. Prednisone antagonises the vitamin D effect in calcium absorption from the digestive apparatus (osteoporosis manifestation) and it stimulates hydrochloric acid release. In central nervous system it acts as a promoter, by causing euphoria, psychosis and convulsions.

Prednizon is indicated in: bronchial asthma; rheumatic arthritis; systemic lupus erythematosus; dermatomyositis; collagen diseases (except systemic sclerosis); poliarteritis nodosa; skin diseases, including pemphigus bullosus and pyoderma gangrenosum; acute interstitial nephritis; ulcerative colitis; Crohn's disease; sarcoidosis; rheumatic carditis; haemolytic anemia (autoimmune); acute lymphoid leukemias, malignant lymphoma; multiple myeloma, idiopathic thrombocytopenic purpura; immunosuppressant etc.

2. BEFORE YOU TAKE PREDNIZON

Do not take Prednizon:

- if you are allergic to prednisone or to any of the excipients of Prednizon tablets;
- if you have a systemic fungal infection;
- if you have immunization with live viruses;
- if you have acute tuberculosis.

If you think any of these applies to you, do not take the tablets, talk to your doctor first and follow the advice given.

Take special care with Prednizon

Tell your doctor:

- if you are pregnant, planning to become pregnant, or are breast-feeding;
- if you are taking any prescription or nonprescription medicine, herbal preparation, or dietary supplement;
- if you have allergies to medicines, foods, or other substances;
- if you are scheduled for a vaccination with a live virus vaccine (eg, smallpox);
- if you have an underactive thyroid, liver or kidney problems, diabetes, or ulcerative colitis;
- if you have heart problems, esophagitis, gastritis, stomach obstruction or perforation, or an ulcer;
- if you have a history of mental problems, such as depression;
- if you have a herpetic infection in your eye or any other type of infection (bacterial, fungal, or viral); have or recently had tuberculosis (TB) or tested positive for TB, measles, or chickenpox;

- if you have scleroderma (also known as systemic sclerosis, an autoimmune disorder) because daily doses of 15 mg or more may increase the risk of a serious complication called scleroderma renal crisis. Signs of scleroderma renal crisis include increased blood pressure and decreased urine production. The doctor may advise that you have your blood pressure and urine regularly checked.

Children

Because treatment with prednisone can inhibit growth in children, this drug should be used only if the doctor deems it necessary and child growth must be constantly monitored.

Effects of misuse as doping agent

Use of Prednizon may cause positive doping results.

Moreover, use of Prednizon as a doping agent may constitute a health hazard.

Taking other medicines

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines, even those without a prescription.

There are many other medicines that can interact with steroids. Below is only a partial list of these medicines:

- aspirin (taken on a daily basis or at high doses);
- diuretics;
- a blood thinner such as warfarin;
- cyclosporine;
- insulin or oral antidiabetic drugs;
- antibiotics such as rifampin, or troleandomycin; or antiepileptic drugs such as phenytoin or phenobarbital.

This list is not complete and there may be other drugs that can interact with Prednizon. Tell your doctor about all the prescription and over-the-counter medications you use. This includes vitamins, minerals, herbal products, and drugs prescribed by other doctors. Do not start using a new medication without telling your doctor.

Taking Prednison with food or drinks

Avoid drinking alcohol during treatment. Take the drug with food.

Pregnancy

This medication may be harmful to the unborn baby. Tell your doctor if you are pregnant or plan to become pregnant during treatment.

Breastfeeding

Prednison can pass into breast milk and may harm a nursing baby. Do not use this medication without telling your doctor that you are breastfeeding a baby.

Driving and using machines

This medicinal product has minor influence on the ability to drive and use machines.

Important information about some of the ingredients of Prednison tablets

This medicine contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. HOW TO TAKE PREDNISON

Take this medication exactly as it was prescribed for you. Do not take the medication in higher doses, or take it for longer than recommended by your doctor.

Your doctor may occasionally change your dose to make sure you get the best results from this medication.

You should take Prednison by mouth, with food to avoid stomach upset.

The dose of Prednison should be individualized according to the severity of the disease and the response of the patient.

Adults: the dose depends on the type of the disease, the severity of disease and clinical response.

Short-treatment: 20 – 30 mg every day, for a few days; daily dose decreases with 2.5 or 5 mg, every 2 to 5 days, depending on clinical response.

Rheumatoid arthritis: 7.5 to 10 mg per day. The dose should be reduced to the lowest level that ensures an adequate clinical response.

For most other diseases are used 10 to 100 mg per day for 1 to 3 weeks; and then the dose is reduced to the lowest effective dose.

Children: the fractions of adult dose can be used (e.g., 75% for 12 year old, 50% for the 7 year old and 25% for 1 year old), but also the clinical factors should be taken in consideration.

If you take more Prednizon than you should

If you take more Prednizon than you should, or if the children have been taking the medicine by accident, please contact your doctor, the hospital or call the emergency to get an opinion of the risk and advice on the action to be taken.

A single large dose of Prednizon is not expected to produce life-threatening symptoms.

However, long-term use of high steroid doses can lead to symptoms such as thinning skin, easy bruising, changes in the shape or location of body fat (especially in your face, neck, back, and waist), increased acne or facial hair, menstrual problems, impotence, or loss of interest in sex.

If you forget to take Prednizon

If you forget a dose, take the next dose when it is the normal time to take it.

Do not take a double dose to make up for the forgotten dose.

If you stop taking Prednizon

Do not stop taking Prednizon suddenly, or you may have unpleasant withdrawal symptoms. Talk to your doctor about how to avoid withdrawal symptoms when stopping Prednizon.

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, Prednizon can cause side effects in some patients.

Get emergent medical help if you have any of these signs of an allergic reaction: difficulty breathing, swelling of your face, lips, tongue, or throat.

Inform your doctor at once if you have any of these serious side effects:

- problems with your vision;
- swelling, rapid weight gain, shortness of breath;

- severe depression, unusual thoughts or behavior, seizure (convulsions);
- bloody or tarry stools, coughing up blood;
- pancreatitis (severe pain in your upper stomach spreading to your back, nausea and vomiting, rapid heart rate);
- low potassium (confusion, uneven heart rate, extreme thirst, increased urination, leg discomfort, muscle weakness or limp feeling);
- high blood pressure (severe headache, blurred vision, buzzing in your ears, anxiety, confusion, chest pain, shortness of breath, uneven heartbeats, seizure);
- scleroderma renal crisis in patients already suffering from scleroderma (an autoimmune disorder) (unknown frequency). Signs of scleroderma renal crisis include increased blood pressure and decreased urine production.

Less serious side effects may include:

- sleep problems (insomnia), mood changes;
- acne, dry skin, thinning skin, bruising or discoloration;
- slow wound healing;
- increased sweating;
- headache, dizziness;
- nausea, stomach pain, bloating;
- changes in the shape or location of body fat (especially in your arms, legs, face, neck, breasts, and waist).

This is not a complete list of side effects and others may occur. Tell your doctor about any unusual or bothersome side effect.

5. HOW TO STORE PREDNIZON

Keep out of the reach and sight of children.

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

Do not store above 25°C.

Store in the original package in order to protect it from light.

6. FURTHER INFORMATION

What Prednizon contains

The **active substance** is prednisone acetate.

Each tablet contains 5 mg of prednisone acetate.

The **excipients** are: lactose monohydrate, pregelatinized maize starch, talc, sodium lauryl sulphate, sodium starch glycolate.

Contents of the pack

Box with 60 tablets.

Marketing Authorisation Holder (MAH) and Manufacturer:

PROFARMA sh.a.,

St. "Skënder Vila",

Tirana, Albania.

Tel.: +355 4 23 89 602

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