Package leaflet: Information for the patient

Prednisolone Renata 5 mg tablets
prednisolone

Read all of this leaflet carefully before you start taking 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 signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Prednisolone is and what it is used for
2. What you need to know before you take Prednisolone
3. How to take Prednisolone
4. Possible side effects
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1. What Prednisolone is and what it is used for

Prednisolone is a cortisone preparation that counteracts and suppresses allergic complaints, inflammations and rheumatic complaints.

The medicine is used in conditions where you need to dampen the body's reaction, such as the inflammatory reaction of rheumatoid arthritis. Other examples that can be mentioned are disease of the connective tissue (SLE), inflammations of the blood vessel walls, changes in connective tissue, asthma, severe inflammation of the colon (ulcerative colitis), in certain blood diseases, severe allergic conditions and tumour treatment.

Prednisolone contained in Prednisolone may also be approved to treat other diseases not mentioned in this leaflet. Ask your doctor, pharmacist or other healthcare professional if you have any further questions and always follow their instructions.

2. What you need to know before you take Prednisolone

Do not take Prednisolone
- if you are allergic to prednisolone or any of the other ingredients of this medicine (listed in section 6).
- if you have a yeast infection.

You should not be vaccinated with live vaccines while taking immunosuppressive doses of cortisone preparations.

Warnings and precautions
Talk to your doctor or pharmacist before taking Prednisolone if you have:
- an infection or get an infection while you are being treated with Prednisolone
- underactive thyroid gland (also called hypothyroidism)

- liver disease or kidney failure
- or have had seizures
- Myasthenia gravis (a disease that causes muscle weakness)
- tuberculosis or have ever been treated for tuberculosis
- ulcers, duodenal ulcers or an inflammatory bowel disease (e.g. ulcerative colitis or diverticulitis)
- diabetes
- heart disease, e.g. heart failure or high blood pressure
- had blood clots in the past (e.g. vein thrombosis) or easily develop blood clots
- mood swings or psychotic tendencies
- any drug allergy
- bone disease (osteoporosis)
- tumour of the adrenal gland (pheochromocytoma)
- new blood vessels or bowel connections
- scleroderma (also called systemic sclerosis, an autoimmune disease) because daily doses of 15 mg or more may increase the risk of a serious complication called acute kidney crisis. Signs of acute kidney crisis include high blood pressure and reduced urine production. Your doctor may advise you to check your blood pressure and urine values regularly.

Contact your doctor if during treatment:
- you experience serious mental side effects, such as depression and suicidal thoughts. These can also occur when you stop taking Prednisolone.
- you experience blurred vision or other visual disturbances.
- you are subjected to unusually severe physical or mental stress of any kind (e.g. infection, surgery, trauma) while being treated with Prednisolone. The dose may need to be increased.

Prednisolone treatment may reduce your resistance to infections, which makes it easier for you to suffer from infections during treatment. Chickenpox and measles can become more serious when taking cortisone preparations. Therefore, if you have not had these diseases before, avoid exposing yourself to chickenpox or measles during treatment and talk to your doctor if this should still happen.

If you must be vaccinated during Prednisolone treatment, you should inform your doctor about your treatment before you receive the vaccination.

Tumour lysis syndrome may occur when corticosteroids are used in cancer treatment. Tell your doctor if you have cancer and have symptoms of tumour lysis syndrome such as muscle cramps, muscle weakness, confusion, irregular heartbeat, loss of vision or visual disturbances, and shortness of breath.

Corticosteroids can cause growth inhibition in infants, children and adolescents and therefore long-term use should be avoided. If long-term use is necessary, growth in infants and children will be closely monitored by the doctor.

Other medicines and Prednisolone
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.

The treatment effect may be affected if this medicine is taken at the same time as certain other medicines. It is especially important that your doctor knows if you are using any of the following medicines:
- rifampicin, isoniazid (used to treat tuberculosis)
- blood thinners (medicines that affect the ability of the blood to clot)
- carbamazepine, phenobarbital, phenytoin (medicines to treat epilepsy)
- anticholinergics (medicines that counteract the effect of the body's own substance acetylcholine, used for the treatment of e.g. Parkinson's disease and asthma)
- cholinesterase inhibitors (used to treat Myasthenia gravis and Alzheimer's disease)
- insulin and diabetes medicines in the form of tablets. Cortisone preparations may impair the blood sugar lowering effect of diabetes medicines.
- cobicistat (medicine for HIV infection)

- medicines used to treat a range of conditions, known as CYP3A inhibitors (e.g., certain antibiotics like clarithromycin or erythromycin, antifungals like ketoconazole or fluconazole, protease inhibitors like ritonavir, or calcium channel blockers like verapamil or diltiazem)
- oestrogens (used in oral contraceptives, among other things)
- acetylsalicylic acid and other non-steroidal anti-inflammatory drugs (NSAIDs) (used to treat pain and inflammation). The risk of stomach ulcers may be increased when combined with cortisone preparations.
- thiazides, furosemide, etacrynic acid (potassium-lowering diuretic)
- xanthines (e.g. theophylline, used for the treatment of asthma)
- beta-2 stimulants (e.g. salbutamol, terbutaline, salmeterol, formoterol, used for the treatment of asthma)
- amphotericin B (antibiotics for fungal infection).
- methotrexate (used to treat chronic inflammatory conditions or certain cancers). Concomitant use may increase the risk of treatment-related blood disorders.

If you need to be vaccinated, tell your doctor that you are taking Prednisolone.

Pregnancy and breast-feeding
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Pregnancy
There is a risk that the foetus will be affected.
Patients with pre-eclampsia or fluid retention require close monitoring.

Breastfeeding
Prednisolone passes into breast milk, but will most likely not affect babies being breastfed.

Driving and using machines
Dizziness, visual disturbances and fatigue may occur with the use of Prednisolone. If you experience such symptoms, do not drive or use machines.

You are responsible for assessing whether you are fit to drive a motor vehicle or perform work that requires increased attention. One of the factors that may affect your ability in these respects is the use of drugs because of their effects and/or side effects. Description of these effects and side effects can be found in other sections. Therefore, read all the information in this package leaflet for guidance. If you are not sure, discuss with your doctor or pharmacist.

Prednisolone contains lactose (anhydrous)
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

Prednisolone contains sodium benzoate
This medicine contains 0.0675 mg sodium benzoate in each tablet.
Sodium benzoate may increase jaundice (yellowing of the skin and eyes) in newborn babies (up to 4 weeks old).

3. How to take Prednisolone

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

The dose is determined by the doctor, who will adjust it individually for you.

Usually, treatment is started with a higher dose, which is then reduced to a specific maintenance dose when a satisfactory effect is obtained. When stopping treatment, the dose should be slowly tapered to eventually completely stop. Do not stop treatment without consulting a doctor.

A doctor should be contacted in the event of stresses such as fever and stress, as dose change may become relevant.

The tablet is intended to be swallowed whole with water.

If you take more Prednisolone than you should

If you have ingested too much of the drug or if, for example, a child has ingested the drug accidentally, contact a doctor, hospital for an assessment of the risk and advice.

If you forget to take Prednisolone
Do not take a double dose to make up for a forgotten dose.

If you stop taking Prednisolone

If you have been taking Prednisolone for an extended period of time, treatment must be gradually tapered as directed by your doctor. It must not be stopped suddenly, as this can lead to severe side effects.

"Steroid discontinuation syndrome" may occur after sudden discontinuation of Prednisolone. This syndrome includes symptoms such as loss of appetite, nausea, vomiting, fatigue, headache, fever, joint pain, flaky skin, muscle aches, weight loss and/or low blood pressure. Contact your doctor if you experience any of these symptoms after you stop taking Prednisolone.

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 can cause side effects, although not everybody gets them.

Side effects occur mainly in long-term treatment but also depend on dose size and individual sensitivity.

Contact your doctor immediately if the following serious side effects occur:

Severe allergic reaction, including angioedema (occurs in an unknown number of users).
Symptoms may include:
- swelling of the face, tongue or throat
- difficulty swallowing
- hives and difficulty breathing
- fever
- drop in blood pressure.

Pheochromocytosis-related crisis (occurs in an unknown number of users).
Symptoms may include:
- headache attacks
- heart palpitations
- sweating
- paleness.

Acute kidney crisis (in patients already suffering from scleroderma, an autoimmune disease, see section 2, Warnings and precautions) (occurs in an unknown number of users).

Symptoms may include:

- high blood pressure and decreased urine production

Suicidal thoughts (see section 2, Warnings and precautions) (occurs in an unknown number of users).

Other side effects:

Common (may affect up to 1 in 10 people)
- infections, the immunosuppressive effect of Prednisolone may also cause infections to flare up again (e.g. tuberculosis)
- lower concentration of certain hormones, Cushing-like appearance, growth retardation in children
- low levels of potassium, accumulation of sodium in the body, increased sugar in the blood and urine, osteoporosis
- swelling due to fluid retention, high blood pressure
- thinner skin, impaired wound healing
- muscle wasting.

Uncommon (may affect up to 1 in 100 people)
- activation of mental disorder (at high doses)
- cataracts, glaucoma.

Rare (may affect up to 1 in 1 000 people)
- depression
- mania in patients without previous mental illness
- benign increase in pressure in the skull
- degradation of bone, tendon rupture.

Has been reported (occurs in an unknown number of users)
- increase in white blood cells (leukocytosis)
- hypersensitivity to the medicine
- withdrawal syndrome during tapering (see section 3)
- decreased blood pH, decreased blood potassium, increased blood lipids, impaired glucose tolerance, worsened diabetes, accumulation of fatty tissue in isolated places in the body, increased appetite (which may lead to weight gain)
- emotional symptoms (such as exhilaration, emotional instability, drug dependence), , mental disorder (such as delusions, hallucinations, and schizophrenia), personality change, confusion, anxiety, mood swings, abnormal behaviour, sleep problems, irritability
- seizures, memory problems, intellectual disturbance, dizziness, headache, increased amount of fat around the spinal cord
- vision impairment (central serous chorioretinopathy), protruding eyes, blurred vision
- heart failure (in sensitive patients), slow heart rhythm
- blood clots
- hiccoughs
- stomach ulcers, holes (perforation) in the intestine, inflammation of the pancreas, inflammation and ulcers of the oesophagus, swollen abdomen, stomach pains, diarrhoea, digestive problems, nausea
- increased hair in women, bleeding in skin, bruising, redness of skin, sweating, stretch marks (blue-red marks on chest and abdomen), itching, hives, acne
- muscle weakness, muscle aches, broken bones without prior trauma, joint breakdown, joint pain
- irregular periods
- tiredness, malaise
- increased amount of calcium in urine; increased liver values (alanine aminotransferase, aspartate aminotransferase), increased blood alkaline phosphatase, increased blood urea levels (shown in blood samples), weaker reaction to skin tests.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance. Website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Prednisolone

Keep this medicine out of the sight and reach of children.

For HDPE Bottle: This medicinal product does not require any special storage conditions.
For Blister (Alu-PVC; Alu-PVDC): Do not store above 25°C.

Do not use this medicine after the expiry date which is stated on the bottle label, blister and/or carton after EXP. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Prednisolone contains
- The active substance is prednisolone 5 mg per tablet.
- The other ingredients are lactose (anhydrous) 77.80 mg, crospovidone (type A), docusate sodium/sodium benzoate, silica, colloidal anhydrous and magnesium stearate.

What Prednisolone looks like and contents of the pack

Round shaped, white tablets of 6.35 mm in diameter debossed with 'P' on one side and breakline on the other side.
The score line is not intended for breaking the tablet.

Aluminium-PVC or Aluminium-PVC/PE/PVDC blister packs containing 28, 56, 98 or 112 tablets.

HDPE bottles with Child-resistant closure with silica-gel canister containing 25 tablets.
The canister containing the desiccant is not meant to be consumed.

Not all pack sizes may be marketed.

Marketing Authorisation Holder
Renata Pharmaceuticals (Ireland) Limited, 12 Crowe Street, Dundalk, Co. Louth, A91 NN29, Ireland

Manufacturer
ALTERNO LABS d. o. o., Brnčičeva ulica 29, Ljubljana - Črnuče, 1231, Slovenia

This medicine is authorised in the Member States of the European Economic Area under the following names:

Ireland	Prednisolone Renata 5 mg tablets
Portugal	Prednisolona 5 mg comprimidos
Sweden	Pretazon 5 mg tabletter
Norway	Pretazon 5 mg tabletter
Denmark	Pretazon 5 mg tabletter

This leaflet was last revised in July 2026.