Package leaflet: Information for the patient

Prednisolon G.L. Pharma 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 nurse.
- 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 Prednisolon G.L. Pharma is and what it is used for

Prednisolon G.L. Pharma is a cortisone preparation that counteracts and alleviates allergic complaints, inflammations and rheumatic complaints.
The medicine is used in conditions where you must suppress the body's reaction, such as e.g. the inflammatory reaction in joint rheumatism *(rheumatoid arthritis).* Other examples that can be mentioned are connective tissue disease *(SLE),* inflammation of vessel walls, connective tissue changes, asthma, severe inflammation of the large intestine *(ulcerative colitis),* in certain blood diseases, severe allergic conditions and tumour treatment.

2. What you need to know before you take Prednisolon G.L. Pharma

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

Warnings and precautions
Talk to your doctor or pharmacist before taking Prednisolon G.L. Pharma if you have:
- an infection or get an infection while you are being treated with prednisolone
- an underactive thyroid gland *(also called hypothyroidism)*
- a 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
- peptic ulcer, duodenal ulcer 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. venous thrombosis)* or are prone to blood clots
- mood swings or psychotic tendencies

- any drug allergy
- osteoporosis
- tumour of the adrenal gland *(phaeochromocytoma)*
- newly formed blood vessels or intestinal connections
- Scleroderma *(also called systemic sclerosis, an autoimmune disease)* because daily doses of 15 mg or more may increase the risk of a severe complication called an acute kidney crisis. Signs of acute kidney injury include high blood pressure and decreased urine production. The doctor may advise you to check your blood pressure and urine values regularly.

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

Prednisolone treatment can reduce your infection resistance, making you more susceptible to infections during treatment. Chickenpox and measles can become more serious when taking cortisone preparations. If you have not previously had these diseases, you should avoid exposing yourself to chicken pox or measles during treatment and talk to your doctor if this should still happen.

If you must be vaccinated during prednisolone treatment, you must inform the doctor about your treatment before receiving the vaccination.

Tumour lysis syndrome can 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, vision loss or disturbances, and shortness of breath.

Corticosteroids can cause growth retardation in infants, children and adolescents and long-term use should therefore be avoided. If long-term use is necessary, the physician will closely monitor the growth of infants and children.

Other medicines and Prednisolon G.L. Pharma
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 can be affected if this medicine is taken simultaneously with certain other medicines. It is especially important that the doctor knows if you are using any of the following medicines:
- rifampicin, isoniazid *(used to treat tuberculosis)*
- blood-thinning drugs *(drugs that affect the blood's ability to clot)*
- carbamazepine, phenobarbital, phenytoin *(medicines for epilepsy)*
- anticholinergics *(medicines that counteract the effect of the body's substance acetylcholine, used to treat e.g. Parkinson's disease and asthma)*
- cholinesterase inhibitors *(used to treat myasthenia gravis and Alzheimer's disease)*
- insulin and diabetes medicines in tablets. Cortisone preparations can impair the blood sugar-lowering effect of diabetes medicines.
- cobicistat *(medicine for HIV infection)*
- estrogens *(used, e.g. in birth control pills)*
- aspirin and other non-steroidal anti-inflammatory *drugs (NSAIDs) (used to treat pain and*
- *inflammation)*. The risk of stomach ulcers may increase when combined with cortisone preparations.
- thiazides, furosemide, ethacrynic acid *(potassium-lowering diuretics)*
- xanthines *(e.g. theophylline, used to treat asthma)*
- Beta-2 stimulants *(e.g. salbutamol, terbutaline, salmeterol, formoterol, used to treat asthma)*
- amphotericin B *(antibiotic for fungal infection)*.

Tell the doctor you are taking prednisolone, if you must be vaccinated.

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.

Breast-feeding
Prednisolon G.L. Pharma passes into breast milk but is unlikely to affect breastfed children.

Driving and using machines
Dizziness, visual disturbances and fatigue may occur when using Prednisolon G.L. Pharma. If you experience such symptoms, and do not drive or operate machinery.

Prednisolon G.L. Pharma contains lactose
Prednisolon G.L. Pharma contains milk sugar (lactose). If you have been told by your doctor that you have intolerance to some sugars, contact your doctor before taking this medicinal product.

Prednisolon G.L. Pharma contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. How to take Prednisolon G.L. Pharma

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

Prednisolon G.L. Pharma is dosed by your doctor specifically for you.

The tablet can be divided into equal doses.

If you take more Prednisolon G.L. Pharma than you should
If you take more Prednisolon G.L. Pharma than you should talk to a doctor straight away, for example, a child has accidentally ingested the medicine, you should immediately inform your doctor, describing the symptoms.

If you forget to take Prednisolon G.L. Pharma
Do not take a double dose to make up for a forgotten dose.

If you stop to taking Prednisolon G.L. Pharma
If you have taken Prednisolon G.L. Pharma for a longer time period, the treatment needs to be gradually tapered down according to the doctor's instructions. It must not be interrupted suddenly, since this can lead to severe side effects.

"Steroid withdrawal syndrome" may occur after abrupt withdrawal of Prednisolon G.L. Pharma. This syndrome includes symptoms as appetite loss, nausea, vomiting, lethargy, headache, fever, arthralgia, desquamation, myalgia, weight loss and/or hypotension. Contact your doctor if you experience any of these symptoms after ending treatment with Prednisolon G.L. Pharma.

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

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

Contact a doctor immediately if the following serious side effects occur
Severe allergic reactions, including angioedema *(occurs in an unknown number of people).*
Symptoms may include:
- swelling of the face, tongue or throat
- difficulty swallowing
- hives and difficulty breathing
- fever
- blood pressure drop.

Pheochromocytosis-related crisis *(occurs in an unknown number of people).*
Symptoms may include:
- attack-like headache
- palpitation
- sweating
- pallor.

Acute kidney crisis *(in patients already suffering from scleroderma, an autoimmune disease; see section 2, Warnings and precautions) (occurs in an unknown number of people).*
Symptoms may include:
- high blood pressure and decreased urine production

Suicidal ideation *(see section 2, Warnings and precautions) (occurs in an unknown number of people).*

Other side effects

Common (may affect up to 1 in 10 people)
- infections, the immunosuppressive effect of prednisolone can also cause infections to flare up again (eg 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
- breakdown of bone tissue, tendon rupture.

Not known (frequency cannot be estimated from the available data)
- increased number of white blood cells *(leukocytosis)*
- hypersensitivity to the drug
- withdrawal syndrome when tapering off *(see section 3)*
- lowered pH in the blood, decreased amount of potassium in the blood, elevated blood fats, impaired

glucose tolerance, worsened diabetes, accumulation of adipose tissue in isolated places in the body, increased appetite *(which can lead to weight gain)*
- Emotional symptoms *(such as elation, emotional instability, drug addiction)*, mental disorders *(such as delusions, hallucinations and schizophrenia)*, personality change, confusion, anxiety, mood swings, abnormal behaviour, sleep problems, irritability
- seizures, memory problems, intellectual disability, dizziness, headache, increased amount of fat around the spinal cord
- visual impairment *(central serous chorioretinopathy)*, protruding eyes, blurred vision
- heart failure *(in sensitive patients)*, slow heart rhythm
- blood clots
- hiccup
- gastric ulcer, hole *(perforation)* in the intestine, inflammation of the pancreas, inflammation and
- ulceration of the oesophagus, swollen abdomen, stomach pain, diarrhoea, indigestion, nausea
- increased hair growth in women, bleeding into the skin, bruising, reddened skin, sweating,
- stretch marks *(blue-red marks on the chest and abdomen)*, itching, hives, acne
- muscle weakness, muscle pain, bone fracture without previous trauma, joint destruction, joint pain
- irregular periods
- fatigue, malaise
- increased amount of calcium in the urine; increased liver values *(alanine aminotransferase, aspartate aminotransferase)*, increased alkaline phosphatase in the blood, increased levels of blood urea *(seen in blood samples)*, weaker reaction to skin tests.

If any of the side effects become serious or if you notice any not listed in this leaflet, please tell your doctor or pharmacist.

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in Appendix V.* By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Prednisolon G.L. Pharma

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

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

Do not store above 25°C. Store in the original package in order to protect from light.

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 to protect the environment.

6. Contents of the pack and other information

What Prednisolon G.L. Pharma contains
- The active substance is prednisolone. Each tablet contains 5 mg of prednisolone.
- The other ingredients are: lactose monohydrate, cellulose powdered, sodium starch glycolate (Type A), silica, colloidal anhydrous, magnesium stearate.

What Prednisolon G.L. Pharma looks like and contents of the pack
Round, flat, bevelled, white tablets with a break line on one side and debossed with “5” on the other side.

Prednisolon G.L. Pharma 5 mg tablets are available in PVC/PVDC-Aluminium blister packs containing 25 or 100 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer
[To be completed nationally]

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