Package leaflet: Information for the patient

Prednisolon EQL 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, pharmacist 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 EQL Pharma is and what it is used for
2. What you need to know before you take Prednisolon EQL Pharma
3. How to take Prednisolon EQL Pharma
4. Possible side effects
5. How to store Prednisolon EQL Pharma
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1. What Prednisolon EQL Pharma is and what it is used for

Prednisolon EQL Pharma is a corticosteroid that prevents and suppresses allergic disorders, inflammation and rheumatic disorders.
The drug product is used in the states where one needs to suppress the body's response such as inflammatory response in rheumatoid arthritis (RA). Other examples that can be mentioned is a disease of the connective tissue (SLE), inflammation of the vessel walls, connective tissue changes, asthma, severe inflammation of the colon (ulcerative colitis), at certain blood diseases, severe allergic conditions and tumor treatment.

2. What you need to know before you take Prednisolon EQL Pharma

Do not take Prednisolon EQL 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

You should not be vaccinated with live vaccine at the same time as you take immunosuppressive doses of cortisone drugs.

Warnings and precautions:
Talk to your doctor before taking Prednisolon EQL Pharma if you have:

- An infection or get an infection during treatment with prednisolone
- Underactive thyorid gland (also called hypothyroidism)
- Liver disease or renal insufficiency
- Or have had cramp attack
- Myasthenia gravis (a disease that causes muscle weakness)
- Tuberculosis or have ever been treated for tuberculosis

- Ulcers, duodenal gut wound or an inflammatory bowel disease (e.g. ulcerous colitis or diverticulitis)
- Diabetes
- Heart disease, e.g. heart failure or high blood pressure
- Have had thrombus previously (e.g. venous thrombosis) or easily get thrombus
- Mood alterations or psychotic tendencies
- Any drug allergy
- Bone loss (osteoporosis)
- Newly constructed blood vessels or intestinal connections
- Tumor in the adrenal gland (pheochromocytoma)
- 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 acute renal crisis. Signs of acute renal crisis include increased blood pressure and decreased urine production. The doctor may advise that you have your blood pressure and urine regularly checked.

Contact your doctor if you during the treatment
- Experience severe psychological side effects, e.g. depression or suicidal thoughts. These may also occur when you stop taking prednisolon.
- Experience blurred vision or other visual disturbances.- Been exposed to unusually severe physical or psychological stress of any kind during treatment with prednisolone (e.g. infection, surgery, trauma). The dose may need to be increased.

Prednisolone may inhibit your defence against infections, which makes it easier for you to be affected by infections, that ongoing infections may worsen or previous infections may return. Symptoms of an infection may also be masked by prednisolone treatment. Your doctor will monitor you for any infections and consider stopping treatment or reducing the dose as necessary.
Chicken-pox and measles may become more severe when taking cortisone agents. For this reason, you should avoid exposure to chicken-pox and measles during the treatment, if you have not had these diseases previously, and talk to your doctor in case of exposure.

Inform you doctor about your treatment before vaccination, if you need to be vaccinated during the treatment with prednisolone.

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

If oral anticoagulants (medicines taken by mouth to prevent blood clots) are used together with Prednisolone EQL Pharma, the risk of bleeding may increase. In some cases, the effect of oral anticoagulants may also be reduced. Your doctor may need to regularly check your risk of bleeding by performing additional blood tests while you are being treated with Prednisolone EQL Pharma. Your doctor may also adjust the dose of Prednisolone EQL Pharma if necessary.

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

Other medicines and Prednisolon EQL Pharma
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.
The treatment effect can be affected if this drug is taken at the same time as certain other drugs. It is of special importance that the doctor gets to know if you are using any of the following drugs:

- rifampicin, isoniazid (used for treatment for tuberculosis)
- medicines that affect the coagulation (blood's ability to clot)
- carbamazepine, phenobarbital, phenytoin (used for epilepsy)
- anticholinergics (drugs that inhibits the effect of the endogenous substance acetylcholine, used for treatment of e.g. Parkinson’s disease and asthma)
- cholinesterase inhibitors (used for treatment of Myasthenia gravis and Alzheimer’s disease)

- insulin and antidiabetics in form of tablets. Cortisone drugs can impair the blood sugar lowering effect from antidiabetic drugs
- cobicistat (drugs for HIV-infection)
- oestrogens (used e.g. in contraceptive pills)
- acetylsalicylic acid and other non-steroid anti-inflammatory drugs (NSAID) (used for treatment of pain and inflammation). The risk of stomach ulcer may increase at combination with cortisone agents.
- thiazides, furosemide, etacrynic acid (potassium lowering diuretic drugs)
- xanthines (e.g. theophylline, used for treatment of asthma)
- beta-2 agonists (e.g. salbutamol, terbutaline, salmeterol, formoterol, used for treatment of asthma)
- amphotericin B (antibiotic for fungal infection)

If you need to be vaccinated, you should inform your doctor that you take Prednisolon EQL Pharma.

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 is affected.

Breast-feeding
Prednisolone EQL Pharma passes into breast milk but is unlikely to affect breast-feeding infants.

Driving and using machines
Dizziness, visual disturbances and tiredness can occur at treatment with prednisolone. You should not drive or use machinery if you experience these symptoms.

Prednisolone EQL Pharma contains lactose
If you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take Prednisolon EQL Pharma

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, the treatment is initiated with a higher dose that is then reduced to a determined maintenance dose determined when sufficient effect is obtained. When the treatment is to be terminated, the dose should be slowly stepped down and eventually cease.
Do not discontinue the treatment without consulting your doctor.

Doctors should be contacted to shocks such as fever and stress when changing the dose may be considered.

The tablet has a dividing score and can be divided into equal doses.

If you take more Prednisolon EQL Pharma than you should
If you have taken too many tablets, or if a child has taken medicine by accident, contact a doctor or the Hospital Emergency Department for the assessment of the risk and advice.

If you forget to take Prednisolon EQL Pharma
Do not take a double dose to make up for a forgotten dose. Take the next dose at the usual time.

If you stop to take Prednisolon EQL Pharma
If you have taken Prednisolon EQL 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 EQL 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 EQL 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, Prednisolon EQL Pharma can cause side effects, although not everybody gets them.
Side effects mainly occur with long-term treatment, but also depends on the dose and the individual sensitivity.

Immediately contact your doctor if the following severe side effects occur:
Severe allergic reaction, including angioedema (frequency cannot be estimated from available data)
Symtoms may include:
- Swelling of face, tongue or pharynx
- Difficulities to swallow
- Nettle rash or breathing difficulities
- Fever
- Decreased blood pressure

Pheochromocytoma related crisis (frequency cannot be estimated from available data)
Symptoms may include:
- Attacks of headache
- Heart palpitation
- Sweating
- Paleness

Acute renal crisis (among patients already suffering from scleroderma, an autoimmune disease, see section 2, Warnings and precautions) (frequency cannot be estimated from available data)
Symptoms may include:
- high blood pressure and decreased urinary production

Suicidal thoughts (see section 2, Warnings and precautions) (frequency cannot be estimated from available data)

Other side effects:

<u>Common side effects (may affect up to 1 in 10 users):</u>
- Infections, prednisolone´s immunosuppressive effect may also result in that infections flare up again (e.g. tuberculosis)
- Lower concentration of some hormones, Cushing-like appearance, growth retardation in children
- Low levels of potassium, accumulation of sodium in the body, elevated blood and urinary sugar levels, osteoporosis
- Swelling due to fluid retention, high blood pressure
- Thinner skin, impaired wound healing
- Muscular dystrophy

<u>Less common side effects (may affect up to 1 in 100 users):</u>
- At high doses activation of mental disorders
- Glaucoma
- Cataract

Rare side effects (may affect up to 1 in 1000 users):
-Depression
- Mania among patients without previous mental disease
- Benign increase in pressure in the skull
- Osteonecrosis,
- Tendon rupture

Have been reported (frequency cannot be estimated from available data):
- Increased white blood cells (leukocytosis)
- Hypersensitivity to drug
- Withdrawal syndrome at dose reduction (see section 3)
- Decreased pH in blood, decreased amount of potassium in blood, increased blood lipids, impaired glucose tolerance, impaired diabetes, accumulation of fat on separated locations in the body, increased appetite (may lead to weight increase)
- Emotional symptoms (such as exhilaration, emotional instability, drug dependence), psychological disturbance (such as delusions, hallucinations, and schizophrenia), personality alterations, confusional state, anxiety, mood alterations, behavioural disturbances, sleeping disturbances, irritability
- Attacks of cramp, memory disturbances, intellectual disturbance, dizziness, headache, increased fat amount around the spinal cord
- Visual impairment (central serous chorioretinopathy), protruding eyes, blurred vision
- Heart failure (among sensitive patients)
- Slow heart rate
- Thrombus
- Hiccup
- Stomach ulcer, hole (perforation) in intestine, inflammation in pancreas, inflammation and ulcer in oesophagus, swollen abdomen, stomach pain, diarrhoea, digestion difficulties, nausea
- Increased hair growth among women, skin bleedings, bruises, skin redness, sweating, skin ruptures (blue-red marks on the chest and abdomen), itching, nettle rash, acne
- Muscle weakness, muscle ache, bone fracture without precedent trauma, joint degradation, joint ache
- Irregular menstruation
- Tiredness, malaise
- Increased amount of calcium in urine; elevated liver values (alanine aminotransferase, aspartate aminotransferase), elevated alkaline phosphatase in blood, elevated amount of blood urea (detected in blood samples), weaker reaction on skin tests.

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. 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 EQL Pharma

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

Blister: Store below 25°C.
Bottle: This medicinal product does not require any special storage conditions.

To be used before the expiry date printed on the carton label and blister 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 Prednisolon EQL Pharma contains
- The active substance is prednisolone 5 mg.
- The other excipients are:
- Lactose monohydrate
- Maize starch
- Magnesium stearate.

What Prednisolon EQL Pharma looks like and contents of the pack

White, round, flat tablets, 7 mm in diameter

PVC/PVdC/aluminium blister pack: 25 tablets

HDPE bottle with a white PP screw-cap with tamper evident ring: 105 tablets

Not all pack sizes may be marketed.

Marketing Authorisation Holder

[To be completed nationally]

Manufacturer

[To be completed nationally]

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