

Package leaflet: Information for the patient

Predicor 5 mg, 10 mg, 20 mg and 50 mg Tablets

Prednisone

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 Predicor is and what it is used for
2. What you need to know before you take Predicor
3. How to take Predicor
4. Possible side effects
5. How to store Predicor
6. Contents of the pack and other information

1. What Predicor is and what it is used for

Therapeutic indications

This medicine is a corticosteroid (also called a steroid, a type of anti-inflammatory drug). This medicine is available for adults and children over 6 years of age and weighing more than 20 kg. This medicine, known for its anti-inflammatory effect, is used to treat many diseases such as inflammatory disorders and allergies. A high dose of this medicine decreases your immune system response and is therefore used to prevent or treat the rejection of a transplanted organ.

2. What you need to know before you take Predicor

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

Do not take Predicor:

- If you are allergic to prednisone or any of the other ingredients of Predicor, listed in section 6.
- If you have an infection.
- If you are suffering from a viral disease (viral hepatitis, chickenpox) or any recurrent infection (herpes, shingles).
- If you have mental disorders that are not being treated.
- If you need to get vaccinated with a live attenuated vaccine (for example against measles, chickenpox, yellow fever, etc.).
- In children under 6 years of age as they may swallow the tablet the wrong way and choke.

Warnings and Precautions

This medicine should be taken under strict medical supervision.

Prior to treatment, tell your doctor:

- If you have been recently vaccinated
- If you have a stomach ulcer, a large bowel disorder, or if you have recently had surgery for a bowel disease
- If you are diabetic (too high blood sugar), or suffer from high blood pressure
- If you have an infection (especially if you have ever had tuberculosis)
- If you suffer from a decrease in kidney or liver functions
- If you suffer from osteoporosis (bone disease that causes bone fragility) and myasthenia gravis (muscle disease resulting in muscle weakness)
- If you have been in tropical, subtropical or southern European regions, given the potential risk of parasitic disease
- If you have a disease affecting the adrenal glands known as Cushing's Syndrome
- If you have kidney problems or high levels of uric acid in your blood before starting treatment with Predicor. Tell your doctor if you show symptoms of tumor lysis syndrome such as muscle cramps, muscle weakness, confusion, loss of vision or visual disturbances, shortness of breath, seizures, irregular heartbeat or kidney failure (decreased amount of urine or darkening of the urine) in case you suffer from a hematological malignancy (see section 4 "Possible side effects").

Talk to your doctor before taking Predicor if you suffer from:

- Scleroderma (also known as systemic sclerosis, an autoimmune disease), as daily doses of 15 mg or higher may increase the risk of developing a serious complication called scleroderma renal crisis. Signs of scleroderma renal crisis include high blood pressure and low urine output. Your doctor may advise you to get your blood pressure and urine checked on a regular basis.

During and following treatment:

- Tell your doctor immediately if you experience pain in the tendons (especially pain experienced during physical activities), as this drug can increase the incidence of tendon injury or exceptionally, tendon rupture.
- This medicine can also cause the onset of seizures associated with pheochromocytoma (tumor of the adrenal glands) and which can be life-threatening.
- Avoid contact with people suffering from chickenpox or measles, these diseases can be particularly serious in patients treated with Predicor.
 - Tell the doctor that you are taking or have taken this medicine (for a period of one year after stopping treatment) if you need to undergo an operation or if you are in a stressful situation (fever, illness).
 - Our doctor may advise you to follow a diet, particularly low in salt and sugar, and high in protein.
 - If treatment is prolonged, your doctor will also prescribe calcium and vitamin D intake.
 - In case of prolonged treatment, discontinuation of Predicor must be done gradually to prevent the occurrence of some adverse reactions.
 - Contact your doctor if you experience blurred vision or other visual disturbances.

Other medicines and Predicor

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

You should never take Predicor if you need to be vaccinated with a live attenuated vaccine.

Unless otherwise advised by your doctor, Predicor and medicines containing aspirin (acetylsalicylic acid) at doses greater than or equal to 1 gram per dose and/or 3 grams per day, strong inhibitors CYP3A and mifamurtide, should not be used concomitantly.

Tell your doctor if you are taking any of the following medicines:

- Potassium-lowering drugs (medicines used to lower potassium levels in the blood);
- Oral anticoagulants (medicines used to thin the blood and prevent the formation of blood clots in the circulatory system)
- Enzyme-inducing antiepileptic drugs (medicines that can stimulate the activity of liver enzymes that are involved in metabolism, i.e. the breakdown of other medicinal substances)
- Cobimetinib
- Digoxin (medicines used to improve the strength and efficiency of the heart muscle or to regulate heart rhythm)
- Isoniazid (antitubercular medications)
- Fluoroquinolones (medicines used to treat bacterial infections)
- Aspirin (acetylsalicylic acid) at doses greater than or equal to 500 milligrams per dose and/or less than 3 grams per day
- Non-steroidal anti-inflammatory drugs (medicines used to treat pain or fever)
- Heparins
- Gastrointestinal topicals, antacids and adsorbents

Some medicines can increase the effects of Predicor and your doctor may want to monitor you carefully if you are taking these medicines (including medicines used to treat HIV infection: ritonavir, cobicistat).

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or plan to become pregnant, ask your doctor or pharmacist for advice before taking this medicine.

Pregnancy

This medicine should not be used during pregnancy unless it's strictly necessary and indicated by your doctor.

If you find out that you are pregnant during treatment, consult your doctor who is the sole judge as to whether you should continue this treatment.

Breast-feeding

This medicine passes into breast milk. Therefore, breast-feeding is not recommended during treatment.

Driving and using machines

Not applicable.

Predicor contains lactose

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 Predicor

Posology

This medicine is available for adults and children over 6 years of age and weighing more than 20 kg. More suitable forms are available for children under 6 years of age and weighing less than 20 kg.

Your doctor will determine the dose you should be using, according to your weight and the condition that is being treated.

It is strictly individual.

Administration mode

This medicine is taken orally.

Swallow the tablets with a glass of water, preferably during a meal, once in the morning.

Duration of treatment

Your doctor will determine the duration of your treatment.

It is very important to adhere to the prescribed treatment and not to change it or stop it suddenly without consulting with your doctor first.

In case of prolonged treatment, follow the recommendations of your doctor for dose reduction.

If you take more Predicor than you should

Consult your doctor or pharmacist immediately.

If you take more Predicor than you should, more serious side effects may occur, especially those related to the endocrine system (system responsible for hormone production), the metabolism and the electrolyte balance.

If you forget to take Predicor

For the medicine to be efficient, it must be used regularly. However, if you forget to take a dose, continue treatment as normal.

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 everyone gets them.

This medicine, which is crucial for your health, is generally well tolerated if you follow the recommendations, in particular the diet low in salt and sugar, and high in protein (see also section "Warnings and precautions").

However, depending on the dose and the duration of the treatment, it can cause some adverse effects:

- Severe allergic reactions which may include heart rhythm disturbances, difficulty breathing, low or high blood pressure, sudden and rapid drop in blood pressure, cardiac arrest, skin rashes, weakened immune system making the body less able to defend itself against infections (which may lead to the reoccurrence of an existing infection or increase the risk of serious complications after vaccination).
- Increase in the number of white blood cells.
- The brain's hormone production system loses its ability to self-regulate.
- Changes in your test results (salt, sugar, potassium) which may require a diet or additional treatment
- Acid-base disorders.
- Bruising or developing small red spots on the skin.
- Increase in blood pressure, water and salt retention which can lead to heart failure.
- The heart becomes unable to pump blood properly to the rest of the body (congestive heart failure).
- Mood disorders (excitement, euphoria), sleep disorders (common).
- Severe mental illness which may be manifested in losing touch with reality, thought disorder, speech disorder and delusional thinking (psychosis).
- A spectrum of disorders known as Cushing's syndrome which can result in weight gain, swelling and redness of the face, excessive growth of hair.
- Decreased glucose tolerance, diabetes.
- Bone weakness (osteoporosis, fractures).
- Painful bone fractures in the hip joint (osteonecrosis).
- Adrenal insufficiency, when the glands located on top of the kidneys (adrenal glands) don't produce enough hormones.
- Growth delay in children.
- Menstruation disorders.
- Inability to get or keep an erection (impotence) and reduced libido in men.
- Muscle weakness, tendon rupture especially if Predicor is combined with some antibiotics (fluoroquinolones).
- Digestive disorders: digestive ulcer, bleeding and gastrointestinal perforations, inflammation of the pancreas especially in children.
- Weakening of the skin, delayed healing, acne.
- Spatial and temporal disorientation (confusion), seizure, depression due to treatment discontinuation.
- Sight disorders that can lead to blindness: blurred vision, some types of glaucoma (high fluid pressure in the eye) and cataract (clouding of the lens in the eye), chorioretinopathy (a disease of the retina), complications in patients whose cornea is infected by herpes simplex virus.
- Endocrine disorders (hormonal disorders): onset of fits associated with pheochromocytoma (tumor of the adrenal glands) and which can put your life in danger.
- Scleroderma renal crisis in patients already suffering from scleroderma (an autoimmune disorder). Signs of scleroderma renal crisis include high blood pressure and low urine output.
- Heart diseases: enlarged heart muscle in premature infants.
- Increased pressure in the brain.
- Increased risk of fat buildup in blood vessels, which can form blood clots and clog blood vessels.

Not known (frequency cannot be estimated based on the available data):

- Cases of tumor lysis syndrome have been reported in patients with hematological malignancy. Tumor lysis syndrome may be detected by your doctor based on changes in blood tests such as the increase of uric acid, potassium, or phosphorus levels as well as the decrease of calcium levels, and may lead to symptoms such as muscle cramps, muscle weakness, confusion, vision loss or visual disturbances, shortness of breath, seizures, irregular heartbeat or kidney failure (decreased amount of urine or darkening of the urine). If you experience such symptoms, you should tell your doctor immediately (See section 2 "Warnings and precautions").
- Slow heart rate.

Reporting 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. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Predicor

- 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 blister and the outer packaging. The expiry date refers to the last day of that month.
- Do not store above 30°C. Keep away from humidity.
- Do not use this medicine if you notice visible signs of deterioration.
- Do not throw away any medicines via wastewater. 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 Predicor contains

- The active substance is prednisone.
- Predicor 5 mg: each tablet contains 5 mg prednisone
- Predicor 10 mg: each tablet contains 10 mg prednisone
- Predicor 20 mg: each tablet contains 20 mg prednisone
- Predicor 50 mg: each tablet contains 50 mg prednisone

The other ingredients are lactose, microcrystalline cellulose, magnesium stearate, sodium lauryl sulfate, maize starch, colloidal silicium dioxide.

What Predicor looks like and contents of the pack

Predicor 5, 10, 20 and 50 mg tablets are white round tablets scored into two on one side.

- Predicor 5 mg is available in boxes containing 30 tablets.
- Predicor 10 mg is available in boxes containing 40 tablets.
- Predicor 20 mg is available in boxes containing 20 tablets.
- Predicor 50 mg is available in boxes containing 20 tablets.

Marketing Authorisation Holder and Manufacturer

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Reg. N°. in Lebanon for Predicor 5 mg in Lebanon: 27587/94

Reg. N°. in Lebanon for Predicor 10 mg in Lebanon: 27588/94

Reg. N°. in Lebanon for Predicor 20 mg in Lebanon: 27589/94

Reg. N°. in Lebanon for Predicor 50 mg in Lebanon: 27590/94

This is a Medicament

- Medicament is a product which affects your health and its consumption contrary to an instruction is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the Pharmacist who sold the medicament.
- The doctor and the pharmacist are the experts in medicines, their benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.
- Keep all medicaments out of reach of children.