

PACKAGE LEAFLET: INFORMATION FOR THE USER

PRONISON

20 mg Tablets

PREDNISONE

• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • 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 •

What is in this leaflet?

1. What Pronison is and what it is used for
2. Before you take Pronison
3. How to take Pronison
4. Possible side effects
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1. WHAT PRONISON IS AND WHAT IT IS USED FOR

Pronison is medicine from the group of synthetic corticosteroids that are by the contents and effect similar to the natural hormone of the adrenal cortex. The medicine Pronison is used as a symptomatic treatment of inflammatory diseases, allergic conditions and immune disorders.

Connective tissue disorders:

deterioration of systemic diseases, particularly disseminated lupus erythematosus, inflammation of large number of muscles, blood vessel inflammation, visceral sarcoidosis.

Skin diseases:

severe autoimmune bullous diseases, especially pemphigus and bullous pemphigoid, severe forms of angioma (benign tumor of blood or lymphatic vessels) in infants, lichen planus (lichen planus), acute hives, severe forms of neutrophilic dermatoses.

Gastrointestinal disorders:

aggravation of inflammatory colon bleeding and Crohn's disease, autoimmune chronic active hepatitis (with and without cirrhosis), severe acute hepatitis in alcoholics (histologically confirmed).

Endocrine disorders:

severe subacute De Quervain's thyroiditis (inflammation of the thyroid gland), increased level of calcium in the blood.

Blood disorder:

severe immune thrombocytopenic purpura (effusion of blood in the skin and mucous membranes), autoimmune hemolytic anemia, concomitant use with chemotherapy malignancies of lymphoid tissue, acquired or hereditary chronic erythroblastopenia.

Infectious diseases

tuberculous pericardial inflammation and severe forms of tuberculosis, pneumonia caused by *Pneumocystis carinii* with severe hypoxia (lack of oxygen in tissues).

Neoplastic diseases

antiemetic therapy during chemotherapy, inflammation and swelling in connection with antineoplastic therapy (radiotherapy and chemotherapy).

Kidney disease:

nephrotic syndrome with minimal glomerular lesions, nephrotic syndrome due to focal segmental glomerulosclerosis, III and IV stage of lupus kidney inflammation, granulomatous sarcoidosis, vasculitis with renal impairment, capsular primary glomerulonephritis.

Neurological disorders:

myasthenia gravis, cerebral edema caused by tumors, inflammatory, idiopathic, chronic polyradiculoneuritis, infantile spasms (West Syndrome) / Lennox-Gastaut syndrome, exacerbation of multiple sclerosis (with intravenous corticosteroids).

Ophthalmology:

Heavy front and rear uveitis, edematous exophthalmos, some optic neuropathy (with intravenous corticosteroids) - with these indications, is not recommended for oral administration as a first-line therapy.

Ear, nose and throat:

severe inflammation of the ear, nasal-sinus polyps, acute and chronic sinusitis, short-term treatment of seasonal allergic rhinitis, sub-Glottic laryngitis in children

Respiratory disorders:

persistent asthma (preferably short-term therapy, in case of failure of inhalation therapy with high doses of corticosteroids), worsening of asthma, particularly severe acute asthma; chronic obstructive pulmonary disease, sarcoidosis, diffuse interstitial pulmonary fibrosis.

Rheumatological disorders:

rheumatoid polyarthritis (inflammation of the arteries) and some polyarthritis, rheumatoid polyarthritis and pseudo-Horton disease, acute rheumatism, severe and persistent cervical-brachial neuralgia.

Organ transplantation and allogeneic stem cell transplantation:

prophylaxis or treatment of organ rejection after transplantation.

2. BEFORE YOU TAKE PRONISON

Do not take Pronison:

- If you have a serious untreated infection,
- If you have a viral infection (viral hepatitis, herpes, chickenpox, the rash)
- If you have an untreated psychosis,

- If you have been vaccinated with a live vaccine,
- If you are allergic to prednisone or any of the other ingredients of the medicine (see section 6).

Take special care with Pronison:

- If you have recently been vaccinated,
- If you have a stomach ulcer or duodenal ulcer,
- If you have a disease of the colon or have recently had a surgical intervention in the region of intestine,
- If you have diabetes,
- If you have high blood pressure,
- If you have an infection (especially if you suffer or have suffered from tuberculosis)
- If you have impaired kidney function or liver,
- If you have osteoporosis (thinning of the bones)
- If you suffer from myasthenia gravis (muscle disease accompanied by fatigue)
- If you have stayed in the tropical, subtropical regions, or in the south of Europe, due to the risk of parasitic diseases.

During and after application of the medicine Pronison:

- Tell your doctor if you feel pain in the tendons, because this medicine can affect the formation of tendinopathy, even cracking of tendon
- Avoid contact with persons suffering from chickenpox or rubella,
- In the case of prolonged treatment, never suddenly stop the treatment, but follow doctors' recommendations for a gradual reduction of dose.
- In the case of stress (eg, surgery and high temperatures, accident) immediately inform your doctor about the use of this product,
- The doctor will advise you to follow a special diet, with less salt, sugar and plenty of protein.

In the case of prolonged treatment, you will be prescribed an additional intake of calcium and vitamin D.

If you have any questions, please contact your doctor or pharmacist.

Taking other medicines

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines that you buy without a prescription and herbal medicines.

- Oral anticoagulants (medicines that prevent blood clotting)
- Medicines that can cause a reduction in serum potassium levels such as some medicines for expelling fluids, stimulating laxatives, amphotericin B (when given into a vein), and others,
- The medicines used in the treatment of epilepsy, such as carbamazepine, phenytoin, primidone,
- Digitalis glycosides (eg, digoxin) used in the treatment of heart failure,
- Medicines to treat diabetes such as insulin, metformin, sulfonamides,
- Medicines for the treatment of tuberculosis, such as isoniazid, rifampicin,
- Medicines for the treatment of cardiac arrhythmias such as antiarrhythmics of the group IA and group III, bepridil, cisapride, Diphemanil, intravenous erythromycin, halofantrine, lumefantrine, methadone, mizolastine, moxifloxacin, pentamidine, intravenous spiramycin and others,
- Neuroleptics (for the treatment of psychiatric disorders),
- Medicines to treat high blood pressure,
- Antibiotics of the fluoroquinolone,
- Acetylsalicylic acid (aspirin)
- NSAIDs (for the treatment of inflammatory conditions, pain and fever).

Avoid taking the medicine if you are almost Pronison vaccinated live attenuated vaccine or you are on aspirin therapy doses

- 1 g per dose, and / or

- 3 g per day.

This medicine contains an active principle which may show a positive reaction to the tests that are performed during the anti-doping control.

Taking food and drink with PRONISON

With chronic administration of Pronison you should apply a special diet with plenty of protein and fewer carbohydrates that are rapidly absorbed.

Pregnancy and breastfeeding

Pregnancy

This medicine is not used during pregnancy unless it is necessary, which will be assessed by your doctor.

If during the application of this medicine you discover that you are pregnant, you should inform your doctor, because only s/he can decide on the continuation of treatment.

Breastfeeding

Do not take the medicine if you are breast feeding, because this medicine is excreted through breast milk.

Driving and using machines

There are no known effects.

Other warnings

In case of intolerance to some sugars, contact your doctor before taking this medicine, as it contains lactose.

3. HOW TO TAKE PRONISON

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you. Check with your doctor or pharmacist if you are not sure.

This medicine is intended for adults and children older than 6 years.

The medicine Pronison is used to treat striking doses and short-term treatment of moderate to high doses, adult and children's body weight greater than 20 kg. For maintenance therapy, the treatment doses of less than 20 mg per day and treatment of children younger than 6 years, there are more convenient dosage forms of the medicine.

The dose you should take will be determined by your doctor depending on the severity and type of disease. The dose is strictly individual. It is very important that you follow the treatment, do not change it, nor abruptly interrupt without prior consultation with the doctor.

Method of administration

The medicine is administered orally.

Swallow the tablets with a little water, preferably in the morning, during a meal.

Do not take higher or lower dose than what your doctor has prescribed.

Doctor will advise you how long to take this medicine. In the case of prolonged treatment, you should not abruptly discontinue treatment, but follow doctors' recommendations for a gradual reduction of dose.

If you have any doubts, consult your doctor or pharmacist.

If you take more Pronison than you should

Contact your doctor. If possible, bring a tablet, this instruction or packaging with you to show the doctor what you have taken.

If you forget to take Pronison

If you miss a dose, take it as soon as you remember. Do not take a double dose to make up for a forgotten dose.

If you stop taking Pronison

Do not stop taking PRONISON unless your doctor advises you to do so.

If you have any further questions about the application of Pronison, talk to your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Pronison may cause side effects.

The medicine is usually well tolerated if used in accordance with the recommendations, especially if proper diet is respected.

However, Pronison medicine may cause, depending on the dosage and duration of treatment, more or less severe side effects.

Disturbance of water-electrolyte balance:

reduced levels of potassium, metabolic alkalosis, increase in blood pressure, water retention and salt, which can cause heart failure

Endocrine and metabolic disorders:

iatrogenic Cushing's syndrome, inhibition of secretion of ACTH, occasionally irreversible atrophy of the adrenal cortex, impaired glucose tolerance, latent diabetes, growth retardation in children, disruption of the menstrual cycle.

Musculoskeletal system:

muscle atrophy preceded by muscle weakness (due to increased protein catabolism), osteoporosis, pathological fractures, especially vertebral fractures, aseptic osteonecrosis of the femoral head (the thigh bone).

Described cases of tendon rupture, particularly during concomitant use of fluoroquinolones.

Gastrointestinal disorders:

stomach ulcers and duodenal ulcers, ulcers of the small intestine, digestive perforation and bleeding;

There have been reports of acute inflammation of the pancreas, especially in children.

Skin and connective tissue disorders:

atrophy of the skin, acne, purpura, subcutaneous bleeding, increased hairiness, delayed wound.

Neuro-psychiatric disorders:

Uncommon: euphoria, insomnia, excitement;

Rare: mania, confusion, seizures (generalized or partial); depression after cessation of therapy.

Function disorders of the eye:

certain forms of glaucoma and cataracts.

If you notice any side effect, talk to your doctor or pharmacist.

5. HOW TO STORE PRONISON

Keep out of reach and sight of children.
Store the medicine at a temperature below 25° C.

Shelf life: 5 years
Pronison must not be used after the expiry date stated on the packaging.

Medicines should not be disposed of via waste water or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What does Pronison contain?

1 tablet contains 20 mg of prednisone.

The other ingredients:

Lactose monohydrate;
Starch, corn;
Povidone;
Cellulose, microcrystalline magnesium stearate.

Pharmaceutical form:

Tablets

Pharmacotherapeutic group:

Glucocorticoids

What Pronison looks like and contents of the pack

Round tablets, flat surfaces, white to yellowish white, with cross-division on one side.

Packing: Two blisters Alu / PVC with 10 tablets (20 tablets) in a box.

Regime of dispensing

The medicine is issued on prescription.

Manufacturer

Galenika ad
Batajnički drum bb
11080 Belgrade-Zemun, Serbia