

PREDNISONE Tablets

Dear patient,

Please read the following instructions carefully. They contain important information about the use of this medicine. If you have any further questions, please ask your doctor or pharmacist.

Information about PREDNISONE

PREDNISONE is available as 5 mg, 10 mg, 20 mg and 50 mg tablets for oral administration. Prednisone is a synthetic adrenocortical steroid drug with predominantly glucocorticoid properties, used for its potent anti-inflammatory effects in disorders of many organ systems. At high doses, it reduces immunologic response.

Prednisone is indicated for the following conditions:

- Endocrine disorders: primary or secondary adrenocortical insufficiency (in conjunction with mineralocorticoids where applicable), congenital adrenal hyperplasia, some forms of hypercalcemia, non suppurative thyroiditis
- Rheumatic disorders: e.g. psoriatic arthritis, rheumatoid arthritis, ankylosing spondylitis, bursitis, acute gouty arthritis, systemic lupus erythematosus, certain cases of vasculitis
- Dermatologic diseases: e.g. pemphigus, bullous dermatitis herpetiformis, severe erythema multiforme, exfoliative erythroderma, mycosis fungoides
- Allergic states: e.g. severe allergic rhinitis, asthma, contact dermatitis, atopic dermatitis, serum sickness, drug hypersensitivity reactions, acute urticaria
- **Ophthalmic** diseases: e.g. uveitis and ocular inflammatory conditions unresponsive to topical corticosteroids
- Respiratory diseases: e.g. symptomatic sarcoidosis, acute exacerbations of chronic obstructive pulmonary disease
- Hematologic disorders: e.g. autoimmune hemolytic anemia, idiopathic thrombocytopenic purpura
- Neoplastic diseases: for the treatment of acute leukemia and aggressive lymphomas, prevention of nausea and vomiting associated with cancer chemotherapy
- Edematous states
- Gastrointestinal diseases: e.g. ulcerative colitis, regional enteritis, Crohn's disease, chronic active hepatitis, severe acute alcoholic hepatitis
- Nervous system: e.g. acute exacerbation of multiple sclerosis
- Prevention or treatment of solid organ rejection

Your doctor may prescribe PREDNISONE for other conditions as well.

The way to take PREDNISONE

Take PREDNISONE as directed by your physician.

PREDNISONE is available in different dosage forms to allow adequate adaptation of the dosage. PREDNISONE tablets are indicated for adults and children 6 years of age and older.

Dosage and duration of treatment are individualized on the basis of the condition under treatment, the severity and prognosis of the disease, the response of the patient and treatment tolerance.

In pediatric patients, the initial dose may vary depending on the specific disease entity being treated.

| Age | Acute treatment | Maintenance treatment |
|-----------------------------------|---|------------------------------|
| Adults | 0.35 to 1.2 mg/kg/day Under exceptional circumstances, higher doses may be required. | 5 to 15 mg/day |
| Children 6 years of age and older | 0.14 to 2 mg/kg/day in three or four divided doses | 0.25 to 0.5 mg/kg/day |

Initial dosage varies from 5 to 60 mg per day in divided doses. In situations of less severity, lower doses will generally suffice while in selected patients higher initial doses may be required.

After a favorable response is noted, your doctor will determine the proper maintenance dosage by decreasing the initial drug dosage in small decrements at appropriate time intervals until the lowest dosage which will maintain an adequate clinical response is reached.

Constant monitoring is needed in regard to drug dosage.

When long-term prednisone therapy is necessary, an alternate-day dosage regimen may be considered.

Do not stop abruptly taking your medicine after long-term therapy without first checking with your doctor. It is recommended that it would be withdrawn gradually rather than abruptly.

For a long-term therapy and at high doses, the first doses may be divided into 2 intakes daily. Afterwards, the dosage may be taken in a single dose preferably in the morning during a meal.

Duration of treatment

The duration of treatment is determined according to the disease process. Do not discontinue the treatment without consulting your doctor.

In case of overdose

In case of intake of high doses of this medication, inform your doctor at once and seek emergency medical attention. General measures should be adopted.

In case of missed dose

Take the missed dose as soon as you remember unless the next intake is near. Go on taking the next scheduled dose as directed. Do not take a double dose at once.

Contraindications

This drug is contraindicated in patients with a history of hypersensitivity to any of the components, and in case of systemic fungal infections.

Precautions

- Inform your doctor in case of thyroid disease; liver disease; peptic ulcer; hypertension; congestive heart failure; renal insufficiency; osteoporosis; diabetes; cataracts; psychosocial disturbances; seizure disorders; tuberculosis; bacterial, viral, parasitic or fungal infections or other medical conditions.
- Dosage adjustment is necessary in some conditions such as remissions or exacerbations of the disease and stress (surgery, infection, trauma).
- When surgery is required, inform the attending physician or anesthesiologist that you are receiving or have recently received glucocorticoids.
- Do not receive any immunizations (vaccines) during treatment without first talking to your doctor.
- Inform your doctor if you develop fever or other signs of infection.
- Persons who are on immunosuppressant doses of corticosteroids should avoid exposure to chickenpox or measles.
- Your doctor may instruct you to follow low-sodium, potassium rich, calcium rich and high protein diet.
- It is recommended to monitor frequently serum potassium levels, glucose level, blood pressure and perform periodic eye examination during long-term treatment with corticosteroids.
- Growth and development of children on prolonged corticosteroid therapy should be carefully observed.
- Caution should be used when administered during pregnancy or lactation.

Associations with other medications

Please inform your doctor if other medicines are being taken or have been taken recently.

Concomitant administration with barbiturates, phenytoin, carbamazepine, phenobarbital, ephedrine, or rifampicin may require dosage adjustment of prednisone.

Caution should be used when administered with sultopride, cyclosporine, estrogens, ketoconazole, oral anticoagulants, aspirin, non-steroidal anti-inflammatory drugs, potassium-depleting diuretics, amphotericin B, digitalis glycosides, or with antidiabetic agents.

Adverse reactions

Complications of treatment with glucocorticoids are dependent on the size of the dose and the duration of treatment.

Some patients may experience side effects when the corticoid is administered at high doses and during long-term treatment such as fluid retention, sodium retention, congestive heart failure, potassium loss, hypertension, muscle weakness, abdominal distention, peptic ulcer, increased sweating, convulsions, headache, vertigo, psychic disturbances, decreased carbohydrate tolerance, development of cushingoid state, hirsutism, osteoporosis, menstrual irregularities, cataracts, glaucoma, impaired wound healing, thin fragile skin and suppression of growth in children.

Prolonged therapy may lead to suppression of pituitary-adrenal function.

Inform your doctor if any side effect appears or becomes bothersome.

Storage

Store at controlled room temperature (up to 25°C), protected from light and humidity, beyond the reach of children.

The expiry date is printed on the pack; don't use this medicine after this date.

Pack Presentation

PREDNISONONE 5 mg, pack of 30 tablets

PREDNISONONE 10 mg, pack of 40 tablets

PREDNISONONE 20 mg, pack of 20 tablets

PREDNISONONE 50 mg, pack of 20 tablets

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