PREDALONE®
15 mg/5 mL Syrup

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 PREDALONE
Each 5 mL contains 15 mg prednisolone (as prednisolone sodium phosphate).
Other ingredients: Methylparaben, propylparaben, disodium EDTA, aspartame, non-crystallizing sorbitol, strawberry flavor, menthol, purified water.
PREDALONE syrup is for oral use.
Prednisolone 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.
Prednisolone is indicated in 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, juvenile rheumatoid arthritis, ankylosing spondylitis, bursitis, acute gouty arthritis, systemic lupus erythematosus, dermatomyositis, certain cases of vasculitis
- Dermatologic diseases: e.g. pemphigus, bullous dermatitis herpetiformis, severe erythema multiforme, exfoliative eryhroderma, 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 and inflammatory exacerbations associated to chemotherapy and radiotherapy
- 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, Lennox-Gastaut syndrome
- Prevention or treatment of solid organ rejection
- Nephrotic syndrome
- Some kinds of otitis, chronic or acute sinusitis
Your doctor may prescribe PREDALONE for other conditions as well.

The way to take PREDALONE
Take PREDALONE as directed by your physician.
PREDALONE syrup is indicated for adult and pediatric patients.
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.
Initial dosage of PREDALONE varies from 5 mg to 60 mg of prednisolone base per day in divided doses. In pediatric patients, the initial dose may vary depending on the specific disease entity being treated.

In situations of less severity, lower doses will generally suffice while in selected patients higher initial doses may be required. The initial dosage should be maintained or adjusted until a satisfactory response is noted.
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.

Age	Acute treatment	Maintenance treatment
Adult patients	0.35 to 1.2 mg/kg/day Under exceptional circumstances, higher doses may be required.	5 to 15 mg/day
Pediatric patients	0.14 to 2 mg/kg/day in three or four divided doses	0.25 to 0.5 mg/kg/day

Constant monitoring is needed in regard to drug dosage.
When long-term prednisolone therapy is necessary, an alternate-day dosage regimen may be considered. 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 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.

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 prednisolone.

Caution should be used when administered with sultopride, cyclosporin, 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, weight gain, 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

PREDALONE, prednisolone 15 mg/5 mL, bottle of 100 mL (with a dosing cup)

Issue date: 06/2010

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