PREDALONE PLUS®
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 PLUS
Each 5 mL contains 10 mg prednisolone (as prednisolone sodium phosphate) and 2 mg of dexchlorpheniramine maleate.
Other ingredients: Sucralose, Sorbitol, Edetate disodium, Glycerin, Potassium phosphate, Sodium saccharin, Sodium chloride, Methyl Paraben, Propyl Paraben, Menthol, Strawberry flavor, Purified water
Sucralose, Sorbitol, Edetate disodium, Glycerin, Potassium phosphate, Sodium
PREDALONE PLUS 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.
Dexchlorpheniramine is an H1-receptor antagonist. It is an alkylamine derivative.
Dexchlorpheniramine antagonizes most of the pharmacological effects of histamine.
PREDALONE PLUS is indicated for the treatment of severe allergic conditions which require the action of an antihistamine and a systemic corticosteroid:
-Perennial and seasonal allergic rhinitis: it relieves sneezing, rhinorrhea, nasal itch and conjunctivitis
-Acute and chronic allergic and inflammatory processes involving the eye such as allergic conjunctivitis, keratitis, nongranulomatous iritis, iridocyclitis, chorioretinitis and uveitis.
-Allergic skin disorders including mild, uncomplicated, acute urticaria and angioedema, pruritus, insect bites, some drug allergies, atopic dermatitis (eczema), and contact dermatitis
-Allergic and non-allergic pruritic symptoms
-Adjunctive therapy in anaphylactic reactions
-Severe chronic asthma and seasonal asthma
Your doctor may prescribe PREDALONE PLUS for other conditions as well.

The way to take PREDALONE PLUS
Take PREDALONE PLUS as directed by your physician.
PREDALONE PLUS syrup is indicated for adult and pediatric patients aged more than 2 years.
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 PLUS will be determined based on prednisolone: 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.

Constant monitoring is needed in regard to drug dosage.
When long-term 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

- This drug should not be used in pediatric patients less than 2 years of age.
- This drug must be used with caution in elderly patients and in patients with a predisposition to urinary retention, increased intraocular pressure, chronic constipation, cardiovascular disease.
- 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.
- This drug may cause marked drowsiness or impair the mental and/or physical abilities required for the performance of potentially hazardous tasks, such as driving a vehicle or operating machinery.

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.

Caution should be used when administered with alcohol, hypnotics, narcotic analgesics, sultopride, cyclosporin, estrogens, ketoconazole, oral anticoagulants, aspirin, non-steroidal anti-inflammatory drugs, potassium-depleting diuretics, amphotericin B, digitalis glycosides, antidepressants, tranquilizers, anti-arrhythmic agents, atropine-like substances 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.

Certain patients may, however, respond to antihistamine drugs by becoming drowsy, dizzy or nauseated. Other possible side effects include restlessness, fatigue, dry mouth, anorexia, blurred vision, constipation and headache.

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 PLUS, bottle of 90 mL (with a dosing cup)

Issue date: 05/2020

For further information, visit our company's web site: www.medipharlabs.com or call the "Consumer Healthcare Service" at 961-4-540056.