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 5mL of PREDALONE PLUS syrup contains 10 mg prednisolone (as prednisolone sodium phosphate) and 2 mg dexchlorpheniramine maleate.
The excipients are: sucralose, sorbitol, edetate disodium, glycerin, potassium phosphate, sodium saccharin, sodium chloride, methyl paraben, propyl paraben, menthol, strawberry flavor and purified water.
PREDALONE PLUS syrup is for oral use.
Prednisolone is a corticosteroid used as an anti-inflammatory medication. At high doses, it reduces the activity of the immune system.
Dexchlorpheniramine maleate is an antihistamine used to reduce allergic symptoms.
PREDALONE PLUS is indicated for the treatment of severe allergic conditions such as:
- Perennial and seasonal allergic rhinitis: it relieves sneezing, runny nose, watery and itchy eyes.
- Skin diseases such as pruritus, psoriasis, urticaria (hives), atopic dermatitis (eczema), contact dermatitis, insect bites and some drug allergies.
- Respiratory Diseases such as allergic asthma and hypersensitivity pneumonitis.
- Ophthalmic diseases and allergies such as allergic conjunctivitis, uveitis and optic neuritis.
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.
Dosage and duration of treatment are individualized and adjusted according to the condition under treatment, the severity of the disease, the patient's response and treatment tolerance.
PREDALONE PLUS syrup is indicated for adults and children 2 years of age and older.
The initial dosage is determined based on the dosage of prednisolone:
- In adult patients, the initial dose is 5 to 60 mg/day in divided doses.
- In pediatric patients, the initial dose is 0.14 to 2 mg/kg/day in 3 or 4 divided doses.
The initial dose should be adjusted and maintained until a satisfactory response is obtained; then, gradually in small decrements at appropriate intervals decrease to the lowest dose that maintains an adequate clinical response.

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 the following condition:
- Hypersensitivity to any of the components

- Systemic fungal infections

Precautions

-Do not stop taking this medicine without first checking with your doctor. The treatment should be discontinued gradually.

- Dosage adjustment is necessary in some conditions such as remissions or exacerbations of the disease and stress (surgery, infection, trauma).
- This drug should be used with caution in elderly patients and in case of liver or kidney disease, hyperthyroidism, heart disease, thyroid disease, hypertension, glaucoma, nonspecific ulcerative colitis, urinary retention, prostate disease, peptic ulcer, osteoporosis, infections or seizure.
- Your doctor may instruct you to follow low-sodium, potassium rich, calcium rich and high protein diet.
- Do not receive any immunizations (vaccines) during treatment without first talking to your doctor.
- Persons who are on immunosuppressant doses of corticosteroids should avoid exposure to chickenpox or measles.
- Inform your doctor if you develop fever or other signs of infection.
- Growth and development of children on prolonged corticosteroid therapy should be carefully observed.
- Avoid drinking excessive amounts of alcoholic beverages during treatment.
- Caution should be taken when driving a car or operating machinery since drowsiness may occur.
- Contact your doctor before using this medication in case of pregnancy or lactation.

Associations with other medications

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

- Do not take this medication if you are taking monoamine oxidase inhibitors (MAOIs) or have taken MAOIs in the previous two weeks.
- Caution should be used with alcohol, sedatives, opioid analgesics, hypnotics, tricyclic antidepressants, potassium-depleting diuretics, ketoconazole, oral anticoagulants, cyclosporine, aspirin, and warfarin.
- Concomitant administration with barbiturates, phenytoin, ephedrine, rifampin or antidiabetic agents may require dosage adjustment.

Adverse reactions

Some patients may experience side effects when the corticosteroid is administered at high doses and during long-term treatment such as fluid and electrolyte imbalance, heart disease, high or low blood pressure, muscle weakness, gastrointestinal disturbances, increased sweating, menstrual irregularities, weight gain, glaucoma, impaired wound healing and suppression of growth in children.

Possible side effects of antihistamine include drowsiness or dizziness, fatigue, loss of appetite, tight chest and dry mouth, nose or throat.

Please inform your doctor if any adverse reaction appears or becomes bothersome.

Storage

Store at controlled room temperature (up to 30°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, Prednisolone 10 mg/5 mL (as Prednisolone Sodium Phosphate), Dexchlorpheniramine maleate 2 mg/5 mL, bottle of 90 mL with a dosing cup.

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