PACKAGE LEAFLET

PREDNISOLON

ATC code: H02AB06

PHARMACOTHERAPEUTIC GROUP

Corticosteroids for systemic use. Glucocorticoids.

COMPOSITION

Prednisolone 5 mg in one tablet.

ACTION

Prednisolon is a synthetic glucocorticoid preparation. It displays strong anti-inflammatory, antiallergic and vasotonic effects. In higher doses, the preparation displays marked immunosuppressive effect. It inhibits the leucocyte and phagocyte migration in the inflammation focus, decreases the capillary permeability and precludes edema formation. The preparation suppresses phagocytosis and also, the release of inflammation mediators. It inhibits the ACTH secretion and suppresses the excretion of gluco- and mineralcorticoids from the adrenal glands. Prednisolon possesses pronounced catabolic effect. Prednisolon increases glycogen accumulation in the liver by inducing the liver glycogenesis and increases glucose utilization in blood. It enhances lipolysis and mobilizes the fatty acids from their stores in fatty tissue, thereby increasing the lipid plasma level. Long-term administration of the preparation results in specific re-distribution of the body fat tissue. Prednisolon diminishes the plasma concentration of Ca$^{2+}$ through reduction in the gastrointestinal absorption of calcium (reduced effect of vitamin D is supposed) and rise in the calcium excretion.
The preparation is quickly and thoroughly absorbed from the gastrointestinal tract following oral administration. It is intensively metabolized, mainly in the liver and less in the kidneys and other tissues. The drug becomes bound to the plasma proteins to a high extent (90-95%). The duration of its effect depends on its biological (tissue) half-life. The drug’s plasma half-life is 2.1-3.5 h, whereas the tissue half-life lasts between 18 and 36 h. Maximum clinical effect is attained within 1-2 h after oral intake and continues for 1.2-1.5 days. The preparation is eliminated predominantly by the kidneys in the form of inactive metabolites.

INDICATIONS

Acute and severe allergic diseases – anaphylactic shock, Quinke’s edema, bronchial asthma, allergic rhinitis, drug and food allergy, serum disease, hay fever, massive urticaria; connective tissue diseases (collagenosis) – in the therapy of acute articular rheumatism, rheumocarditis, system lupus, rheumatoid arthritis, spondylarthritis (Bechterev’s disease), dermatomyositis, Kavazaki’s disease and etc.; atopic dermatitis, contact dermatitis, Stevens-Johnson’s syndrome (erythema multiforme), pemphygus, erythema nodosum, severe forms of psoriasis; ankylosing spondylitis, psoriatic arthritis, Reiter’s syndrome; lymphoid and myeloid leucosis, lymphosarcoma, Hodgkin’s disease, hypoplastic anaemia, hemolytic anaemia; thrombocytopenia; hemorrhagic rectocolitis, Crohn’s disease; chronic active hepatitis, liver insufficiency; as an antiedematous preparation in cerebral edema of various etiology (primary and metastatic tumours, brain operations and etc.); cerebral traumas; multiple sclerosis; myasthenia gravis; choreoretinitis; allergic conjunctivitis; herpes zoster; iridocyclitis; neuritis of optic nerve; pericarditis.
CONTRAINDICATIONS

System mycosis; viral diseases – herpes zoster, hepatitis A, B; osteoporosis, stomach and duodenal ulcer; severe renal impairment; glaucoma; allergy to the preparation, severe psychic disorders.

ADVERSE REACTIONS/SIDE EFFECTS

Nausea, vomiting, meteorism, diarrhea, steroid gastric ulcer; arterial hypertonia, rhythm disturbances; cardiac insufficiency; increased intracranial pressure, headache, vertigo, insomnia, nervous overexcitement; increased intraocular pressure, cataract development; acne, purpura, striae, iatrogenic Cushing’s syndrome, erythematous rash; steroid diabetes mellitus, pancreatitis, retarded growth in children; hypernatremia, hypokalemia, immune suppression, protracted wound healing; osteoporosis, muscle atrophy, post-steroid myopathy, increased sweating, neuropsychic adverse drug effects.

As a rule, adverse effects occur with long-term administration of the preparation.

DRUG AND NON-DRUG INTERACTIONS

Concomitant use of preparations, leading to torsades de pointes is not recommended due to the risk of hypokalemia. Particular attention is needed if administered concurrently with digitalis preparations or other pharmaceuticals, which may bring about hypokalemia.

Co-administration of non-steroid anti-inflammatory preparations increases the risk of gastrointestinal hemorrhages.

Prednisolon enhances the effect of cardiac glycosides and weakens the effect of indirect anticoagulants, tricyclic antidepressants, antidiabetic agents and diuretics.

Oral estrogen-containing contraceptives potentate the effect of Prednisolon. Enzyme
inductors reduce its effect.

Live attenuated vaccines should not be applied during Prednisolon treatment.

**WARNINGS AND PRECAUTIONS**

Administration of Prednisolon in doses, equivalent to 20-30 mg of prednisolon, for 5-7 days or over 30 days in lower doses, may give rise to adrenal insufficiency. The restoration of adrenal function after Prednisolon medication depends on the treatment duration, as well as on the daily dosage employed. Long-term administration of high doses may bring about adrenal gland atrophy. High-protein diet is recommended during the medication, so as to compensate the catabolic effect of the preparation.

Prednisolon medication should be withdrawn gradually.

The preparation should not be administered 8 weeks before or 2 weeks after prophylactic immunization.

In prolonged treatment course (over 3 weeks), monitoring of glucose level in blood and urine and serum electrolyte level is recommended to perform, as well as feces should be checked for occult hemorrhages.

Corticosteroid treatment may aggravate diabetes, osteoporosis, severe arterial hypertension, glaucoma, epilepsy, stomach ulcers and ulcerous colitis.

**PREGNANCY AND BREAST-FEEDING**

Prednisolon must not be administered during pregnancy and breast-feeding, since it passes into the breast milk and may bring about complications in the newborn infant. If pregnancy occurs during the medication, the benefits and risks of taking the drug should necessarily be assessed in each case.
EFFECT ON ACTIVE ATTENTION, ABILITY TO DRIVE AND USE MACHINES

No data have been found of adverse influence on the active attention, reflexes and motor coordination during Prednisolon medication.

DOSAGE AND MODE OF ADMINISTRATION

Adults

The daily dosage is 5-60 mg, as a single dose or divided in several intakes.

Children

500 mcg (0.5 mg)/kg body mass or 15–60 mg/m² body surface daily, divided in 3-4 intakes.

OVERDOSAGE

Prednisolon overdosage may potentate the adverse effects of the preparation. The treatment is symptomatic. If necessary, dosage is reduced or medication is to be discontinued.

PACKAGE

Tablets of 5 mg in packs of 20.

STORAGE

In a dry place, at temperature 15-25°C, protected from light.