PREDNITAB

Tablets

Composition

Prednitab 5 Tablets
Each tablet contains Prednisolone 5 mg.

Prednitab 20 Tablets
Each tablet contains Prednisolone 20 mg.

Action

Prednisolone is a synthetic glucocorticoid with the general properties of the corticosteroids. Prednisolone exceeds hydrocortisone in glucocorticoid and anti-inflammatory activity, being about three times more potent on a weight basis than the parent hormone, but is considerably less active than hydrocortisone in mineralocorticoid activity.
Prednisolone, like hydrocortisone, is a potent therapeutic agent influencing the biochemical behavior of most tissues of the body. The mechanism of action of corticosteroids is thought to be by control of protein synthesis. Corticosteroids react with receptor proteins in the cytoplasm of sensitive cells in many tissues to form a steroid-receptor complex.
Corticosteroids are palliative symptomatic treatment of virtue of their anti-inflammatory effects; they are never curative.

Pharmacokinetics
Absorption
Prednisolone is readily and almost completely absorbed from the GI tract after oral administration.

Distribution
Peak plasma concentrations are obtained 1-2 hours after oral administration. Prednisolone is extensively bound to plasma proteins, although less so than hydrocortisone. Prednisolone crosses the placenta and small amounts are excreted in breast milk.

Metabolism
Prednisolone is mainly metabolised in the liver and has a usual plasma half-life of 2-3 hours. It has a biological half-life lasting several hours which makes it suitable for the alternate-day administration regimens which have been found to reduce the risk of adrenocortical insufficiency, yet provide adequate corticosteroid coverage in some disorders.

Its initial absorption, but not its overall bioavailability, is affected by food, hepatic or renal impairment and certain drugs.

Excretion
It is excreted in the urine as free and conjugated metabolites, together with an appreciable proportion of unchanged prednisolone.

Indications

Rheumatic Disorders
As adjunctive therapy for short-term administration (for acute episode or exacerbation) in ankylosing spondylitis, acute and subacute bursitis, acute non-specific tenosynovitis, acute gouty arthritis, psoriatic arthritis, rheumatoid arthritis including juvenile rheumatoid arthritis (selected cases may require low-dose maintenance therapy), post-traumatic osteoarthritis, synovitis of osteoarthritis and epicondylitis.

Collagen Diseases
In exacerbation or as maintenance therapy in selected cases of systemic lupus erythematosus, acute rheumatic carditis or systemic dermatomyositis (polymyositis).

Dermatological

Pemphigus, bullous dermatitis herpetiformis, severe erythema multiforme, exfoliative dermatitis, mycosis fungoides, severe psoriasis, severe seborrheic dermatitis, angioedema or urticaria, contact dermatitis and atopic dermatitis.

Allergic States
Control of severe allergic conditions intractable to conventional treatment in serum sickness and drug hypersensitivity reactions.

Ophthalmological
Severe, acute and chronic allergic and inflammatory processes involving the eye and its adnexa, such as allergic conjunctivitis, keratitis, allergic corneal marginal ulcers, herpes zoster ophthalmicus, iritis and iridocyclitis, chorioretinitis, anterior segment inflammation, diffused posterior uveitis and choroiditis, optic neuritis and sympathetic ophthalmia.

Respiratory
Symptomatic sarcoidosis, bronchial asthma (including status asthmaticus), Loeffler's syndrome not manageable by other means, berylliosis, fulminating or disseminated pulmonary tuberculosis when used concurrently with appropriate antituberculous chemotherapy, aspiration pneumonitis, seasonal or perennial allergic rhinitis.

Neoplastic Diseases
Palliative management of leukemias and lymphomas in adults and acute leukemia of childhood.

Edematous States
Induction of diuresis or remission of proteinuria in the nephrotic syndrome without uremia, of the idiopathic type or that due to lupus erythematosus.

Gastrointestinal
To tide the patient over a critical period of the disease in ulcerative colitis, regional enteritis (Crohn's disease) and intractable sprue.

Neurological
Acute exacerbations of multiple sclerosis.

Miscellaneous
Tuberculous meningitis with subarachnoid block or impending block when used concurrently with appropriate antituberculous chemotherapy, trichinosis with neurological or myocardial involvement.

Contraindications

- Known hypersensitivity to the drug.
- Systemic fungal infections.
- Administration of vaccines, including smallpox, especially in patients receiving high corticosteroid dosages, is contraindicated because of possible neurological complications and a lack of antibody response.

Warnings

The lowest possible dose of corticosteroid should be used to control the condition being treated. When reduction in dosage is possible, it should be gradual.

In patients receiving corticosteroid therapy subjected to unusual stress, such as trauma or surgery, increased dosage of corticosteroids before, during and after the stressful situation, is indicated. Dietary salt restriction and potassium supplementation may be necessary, especially if this drug is administered in high doses. Calcium levels should be monitored, since corticosteroids increase calcium excretion.

Prolonged use may produce posterior subcapsular cataracts and glaucoma with possible damage to the optic nerves. It may also enhance the establishment of secondary ocular infections due to fungi or viruses. Corticosteroids may mask some signs of infection, and new infections may appear during their use. If an infection occurs during therapy, a suitable antimicrobial agent should promptly control it.

The use of systemic corticosteroids in active tuberculosis should be restricted to cases of fulminating or disseminated disease, where the corticosteroid is used for management of the disease in conjunction with an appropriate antituberculous regimen.

If corticosteroids are indicated in patients with latent tuberculosis or tuberculin reactivity, close observation is necessary as reactivation of the disease may occur. During prolonged corticosteroid therapy, these patients should receive chemoprophylaxis.

Amebiasis, whether latent or active, should be ruled out before therapy with a corticosteroid is instituted in patients prone to the disease, e.g. patients with unexplained diarrhea or patients who have spent time in endemic areas.

Pregnancy
Category B
Animal reproduction studies have failed to demonstrate a risk to the fetus and there are no adequate and well-controlled studies in pregnant women.

Nursing Mothers
Corticosteroids appear in breast milk and can suppress growth, interfere with endogenous corticosteroid production, or cause other unwanted effects. Mothers taking pharmacological doses of corticosteroids should be advised not to breastfeed.

Adverse Reactions

Fluid and Electrolyte Disturbances
Sodium retention, fluid retention, congestive heart failure in susceptible patients, potassium loss, hypokalemic alkalosis and hypertension.

Musculoskeletal
Muscle weakness, steroid myopathy, loss of muscle mass, tendon rupture, osteoporosis, vertebral compression fractures, aseptic necrosis of femoral and humeral heads, pathological fractures of long bones.

Gastrointestinal
Peptic ulcer with possible subsequent perforation and hemorrhage, pancreatitis, abdominal distension and ulcerative esophagitis.

Dermatological
Impaired wound healing, thin fragile skin, petechiae and ecchymoses, facial erythema and increased sweating. Corticosteroids may suppress reactions to skin tests.

Neurological
Convulsions, increased intracranial pressure with papilledema (pseudotumor cerebri) usually after treatment, vertigo and headache.

Endocrine
Menstrual irregularities, development of Cushingoid state, suppression of growth in children, secondary adrenocortical and pituitary unresponsiveness (particularly in times of stress), decreased carbohydrate tolerance, manifestations of latent diabetes mellitus and increased requirements of insulin or oral hypoglycemic agents in diabetics.

Ophthalmological
Posterior subcapsular cataracts, increased intraocular pressure, glaucoma and exophthalmos

Metabolic
Negative nitrogen balance due to protein catabolism.

Cardiovascular
Myocardial rupture following recent myocardial infarction.

Other
Anaphylactoid or hypersensitivity reactions, thromboembolism, weight gain, increased appetite, nausea, malaise and hiccups.

Precautions

Drug-induced secondary adrenocortical insufficiency may be minimized by the gradual reduction of dosage. This type of relative insufficiency may persist for months after discontinuation of therapy. Therefore, in any situation of stress occurring during this period, hormone therapy should be reinstituted. Since mineralocorticoid, secretion may be impaired, salt and/or a mineralocorticoid should be administered concurrently. Corticosteroids have an enhanced effect on patients with hypothyroidism and hepatic cirrhosis. Corticosteroids should be used with caution in patients with ocular herpes simplex because of possible corneal perforation.

Psychic derangements may appear when corticosteroids are used. These can range from euphoria, insomnia, mood swings, personality changes, and severe depression to frank psychotic manifestations. In addition, corticosteroids may aggravate existing emotional instability or psychotic tendencies.

Corticosteroids should be used with caution in nonspecific ulcerative colitis, if there is a probability of impending perforation abscess, or other pyogenic infection, diverticulitis, fresh intestinal anastomoses, active or latent peptic ulcer, renal insufficiency, hypertension, osteoporosis and myasthenia gravis. Growth and development of infants and children receiving prolonged corticosteroid therapy should be carefully observed.

Drug Interactions

Corticosteroids/ Potassium-depleting Diuretics/ Amphotericin B
Concurrent use may enhance hypokalemia; serum potassium level should be determined at frequent intervals.

Corticosteroids/ Cardiac Glycosides
Concurrent use may enhance the possibility of arrhythmias of digitalis toxicity associated with hypokalemia.

Corticosteroids/ Non-steroidal Anti-inflammatory Drugs
The ulcerogenic potential of non-steroidal anti-inflammatory drugs may be increased when used concurrently with corticosteroids.

Corticosteroids/ Hypoglycemics
Corticosteroids may increase blood glucose levels; dosage adjustment of the antidiabetic agent is necessary.

Corticosteroids/ Phenytoin/ Phenobarbital/ Rifampicin/ Ephedrine
Concurrent administration of corticosteroids with one of these drugs may enhance the metabolic clearance of the corticosteroid, resulting in decreased blood levels that require adjustment of dosage.

Corticosteroids/ Salicylates

Corticosteroids may reduce serum salicylate levels by increasing metabolism and/or clearance. Concurrent use requires caution, especially in hypoprothrombinemia.

Corticosteroids/ Anticoagulants
Although reports are conflicting, caution is recommended when these drugs are used together, especially in patients prone to gastrointestinal ulceration and hemorrhage.

Diagnostic Interference
Urine glucose and serum cholesterol levels may be increased.
Decreased serum levels of potassium, triiodothyronine (T3), and a minimal decrease of thyroxin (T4) may occur. Thyroid uptake may be decreased.
Corticosteroids may affect the nitroblue-tetrazolium test for bacterial infection and produce false-negative results.

Dosage and Administration

The maximal activity of the adrenal cortex is between 2 a.m. and 8 a.m.; it is minimal between 4 pm. and midnight. Exogenous corticosteroids suppress adrenocortical activity the least when given at the time of maximal activity (a.m.). Therefore, glucocorticoids should be administered before 9 a.m.
When large doses are given, antacids may be administered between meals to help prevent peptic ulcers.

Initiation of Therapy
The initial dosage depends on the specific disease entity being treated. Initial dosage may vary from 5-60 mg/day.
The initial dosage should be maintained or adjusted until a satisfactory response is noted. If, after a reasonable period of time, there is a lack of satisfactory clinical response, discontinue the drug and transfer the patient to other appropriate therapy.

Dosage requirements are variable and must be individualized. For infants and children, the recommended dosage should be governed by these considerations, rather than by strict adherence to the ratio indicated by age or body weight.

Maintenance Therapy
When the response to the initial dose becomes evident, determine the maintenance dose by titration to the lowest effective level.
Constant monitoring of drug dosage is required. Situations that may make dosage adjustment necessary include changes in the disease process, the patient's individual drug responsiveness, and the effect of patient exposure to stress. In this latter situation, it may be necessary to increase the dosage for a period, consistent with the patient's condition.

Withdrawal of Therapy
If the drug is to be discontinued after long-term therapy, it must be withdrawn gradually to avoid adrenal suppression. If spontaneous remission occurs in a chronic condition, treatment should be discontinued gradually. Continued supervision of the patient after discontinuation of corticosteroids is essential, since there may be a sudden reappearance of severe manifestations of the disease.

Physiological Replacement in Children
Administer 0.1-0.15 mg/kg body weight/day or 4-5 mg/ m2/day, divided into 2 doses (every 12 hours).

Presentation

Prednitab 5 Tablets
Box of 40 tablets

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