PREDO®

(Prednisolone)

ACTIONS:

prednisolone is a glucocorticoid primarily used for its potent anti-inflammatory effects in disorders of many organ systems. Glucocorticoids such as prednisolone cause profound and varied
metabolic effects. In addition, they modify the body's immune responses to diverse stimuli.

INDICATIONS AND USAGE:

PREDO® is indicated in the following conditions:

- Respiratory Diseases

- Symptomatic sarcoidosis
- Loeffler's syndrome not manageable by other means
- Berylliosis
- Fulminating or disseminated pulmonary tuberculosis when used concurrently with
appropriate chemotherapy
- Aspiration pneumonia

- Allergic States

Control of severe allergic conditions not responding to conventional treatment:

- Seasonal or perennial allergic rhinitis
- Atopic dermatitis
- Bronchial asthma
- Serum sickness
- Contact dermatitis
- Drug hypersensitivity reactions
- Dermatologic Diseases
- Pemphigus
- Exfoliative dermatitis
- Bullous dermatitis herpetiformis
- Mycosis fungoides
- Severe erythema multiforme (Stevens-Johnson syndrome)
- Severe psoriasis
- Severe seborrheic dermatitis

-Rheumatic Disorders

As adjunctive therapy for short-term administration in:

- Psoriatic arthritis
- Acute and subacute bursitis
- Rheumatoid arthritis, including juvenile rheumatoid arthritis (for some cases low-dose maintenance therapy is required)
- Acute gouty arthritis
- Acute nonspecific tenosynovitis
- Post-traumatic osteoarthritis
- Ankylosing spondylitis
- Synovitis of osteoarthritis
- Epicondylitis

- Collagen Diseases

During an exacerbation or as maintenance therapy in selected cases of:

- Systemic lupus erythematosus
- Acute rheumatic carditis

- Endocrine Disorders

Primary or secondary adrenocortical insufficiency

- Congenital adrenal hyperplasia
- Hypercalcemia associated with cancer
- Nonsuppurative thyroiditis

- Ophthalmic Diseases

Severe acute and chronic allergic and inflammatory processes involving the eye and its adnexa such as:

- Allergic corneal marginal ulcers
- Allergic conjunctivitis
- Herpes zoster ophthalmicus
- Keratitis
- Anterior segment inflammation
- Chorioretinitis
- Diffuse posterior uveitis and choroiditis
- Optic neuritis
- Sympathetic ophthalmia
- Iritis and iridocyclitis

- Hematologic Disorders

- Acquired (autoimmune) hemolytic anemia
- Erythroblastopenia (RBC anemia)
- Congenital (erythroid) hypoplastic anemia

- Neoplastic Diseases

- Miscellaneous

Tuberculous meningitis with subarachnoid block or impending block used concurrently with appropriate antituberculous chemotherapy. Trichinosis with neurologic or myocardial involvement.
In addition to the above indications PREDO® is indicated for systemic dermatomyositis (polymyositis).

CONTRAINDICATIONS:

Systemic fungal infections.

WARNINGS

Corticosteroids may mask some signs of infection, and new infections may appear during their use.
There may be decreased resistance and inability to localize infection when corticosteroids are used.
Prolonged use of corticosteroids may produce posterior subcapsular cataracts, glaucoma with possible damage to the optic nerves, and may enhance the establishment of secondary ocular infections due to fungi or viruses.
Average and large doses of hydrocortisone or cortisone can cause elevation of blood pressure, salt and water retention, and increased excretion of potassium. These effects are less likely to occur with the synthetic derivatives except when used in large doses. Dietary salt restriction and potassium supplementation may be necessary. All corticosteroids increase calcium excretion.
Persons who are on drugs which suppress the immune system are more susceptible to infections than healthy individuals. Chickenpox and measles, for example can have a more serious or even fatal course in non-immune children or adults on corticosteroids. In such children or adults who have not had these diseases, particular care should be taken to avoid exposure.
If exposed to chickenpox, prophylaxis with varicella zoster immune globulin (VZIG) may be indicated. If exposed to measles, prophylaxis with pooled intramuscular immunoglobulin (IG) may be indicated.
If chickenpox develops, treatment with antiviral agents may be considered
The use of PREDO® in active tuberculosis should be restricted to those cases of fulminating or disseminated tuberculosis in which the corticosteroid is used for the 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.

Vaccination

While on corticosteroid therapy, patients should not be vaccinated against smallpox. Other immunization procedures should not be undertaken in patients who are on corticosteroids, especially on high dose, because of possible hazards of neurological complications and a lack of antibody response.

PRECAUTIONS:

GENERAL Drug-induced secondary adrenocortical insufficiency may be minimized by 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 that period, hormone therapy should be reinstituted. Since mineralocorticoid secretion may be impaired, salt and/or a mineralocorticoid should be administered concurrently.
There is an enhanced effect of corticosteroids on patients with hypothyroidism and in those with cirrhosis. Corticosteroids should be used cautiously in patients with ocular herpes simplex because of possible corneal perforation.
The lowest possible dose of corticosteroid should be used to control the condition under treatment, and when reduction in dosage is possible, the reduction should be gradual.
Psychic derangements may appear when corticosteroids are used, ranging from euphoria, insomnia, mood swings, personality changes, and severe depression, to frank psychotic manifestations. Also, existing emotional instability or psychotic tendencies may be aggravated by corticosteroids.
Aspirin should be used cautiously in conjunction with corticosteroids in hypoprothrombinemia.
Steroids should be used with caution in nonspecific ulcerative colitis, if there is a probability of impending perforation, abscess or other pyogenic infections, diverticulitis, fresh intestinal anastomoses, active or latent peptic ulcer, renal insufficiency, hypertension, osteoporosis, and myasthenia gravis.
Growth and development of infants and children on prolonged corticosteroid therapy should be carefully observed.
Information for Patients: Patients who are on immunosuppressant doses of corticosteroids should be warned to avoid exposure to chickenpox or measles. Patients should also be advised that if they are exposed, medical advice should be sought without delay.

Usage during pregnancy and lactation:

The usage of corticosteroids during pregnancy has not been established. Corticosteroids are not to be used during pregnancy, nursing mothers unless the potential benefit outweighs the potential risks.
Infants born of mothers who have received substantial doses of corticosteroids during pregnancy should be carefully observed for signs of hypoadrenalism

ADVERSE REACTIONS:

Fluid and Electrolyte Disturbances

Sodium retention, Fluid retention, Congestive heart failure in susceptible patients, Potassium loss Hypokalemic alkalosis, Hypertension.

Musculoskeletal

Muscle weakness, Steroid myopathy, Loss of muscle mass, Osteoporosis, Vertebral compression fractures, Aseptic necrosis of femoral and humeral heads, Pathologic fracture of long bones.

Gastrointestinal

Peptic ulcer with possible perforation and hemorrhage, Pancreatitis, Abdominal distention, Ulcerative esophagitis.

Dermatologic

Impaired wound healing, Thin fragile skin, Petechiae and ecchymoses, Facial erythema, Increased sweating, May suppress reactions to skin tests.

Neurological

Convulsions, Increased intracranial pressure with papilledema (pseudo-tumor cerebri) usually after treatment, Vertigo, Headache.

Endocrine

Menstrual irregularities, Development of Cushingoid state, Suppression of growth in children, Secondary adrenocortical and pituitary unresponsiveness, particularly in times of stress, as in trauma, surgery or illness, Decreased carbohydrate tolerance, Manifestations of latent diabetes mellitus, Increased requirements for insulin or oral hypoglycemic agents in diabetics.

Ophthalmic

Posterior subcapsular cataracts, Increased intraocular pressure, Glaucoma, Exophthalmos.

Metabolic

Negative nitrogen balance due to protein catabolism.

DOSAGE AND ADMINISTRATION:

Dosage of PREDO® should be individualized according to the severity of the disease and the response of the patient. For infants and children, the recommended dosage should be governed by the same considerations rather than strict adherence to the ratio indicated by age or body weight.
Dosage should be decreased or discontinued gradually when the drug has been administered for more than a few days.
The initial dosage of PREDO® may vary from 5 mg to 60 mg per day depending on the specific disease entity being treated. If after a reasonable period of time there is a lack of satisfactory clinical response, Prednisolone Syrup should be discontinued and the patient transferred to other appropriate therapy.
After a favorable response is noted, the proper maintenance dosage should be determined 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.
It should be kept in mind that constant monitoring is needed in regard to drug dosage. Included in the situations which may make dosage adjustments necessary are changes in clinical status secondary to remissions or exacerbations in the disease process, the patient's individual drug responsiveness, and the effect of patient exposure to stressful situations not directly related to the disease entity under treatment. In this latter situation it may be necessary to increase the dosage of PREDO® for a period of time consistent with the patient's condition. If after long-term therapy the drug is to be stopped, it is recommended that it be withdrawn gradually rather than abruptly.

PRESENTATION

Syrup:
PREDO® 5 mg : Prednisolone Sodium Phosphate USP 6.7 mg / 5 ml•.
PREDO® 15 mg : Prednisolone Sodium Phosphate USP 20.1 mg / 5 ml•.
•Bottles of 120 ml supplied with a measuring device.
Tablets:
PREDO® 5 mg : Prednisolone 5 mg / Tablet.
PREDO® 25 mg : Prednisolone 25 mg / Tablet.

STORAGE:

Store at room temperature (below 25° C) in a dry place.

ACTIVE INGREDIENTS:

Prednisolone Sodium Phosphate.

EXCIPIENTS: Methyl paraben, Propylene glycol, Glycerin, Disodium Hydrogen Phosphate Anhydrous, Sodium Dihydrogen Phosphate Dihydrate, Disodium Edetate Dihydrate, Sodium Saccharin, Liquid caramel flavor, Raspberry liquid flavor, Sugar crystalline, Allura red FD,C Red No.40, Purified water.

THIS IS A MEDICAMENT

- Medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are experts in medicine, its benefits and risks.
- Do not by yourself interrupt period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.

Keep medicament out of the reach of children

JPI

Revised: 11/2012.
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