**INDICATIONS AND USAGE**

Prednisone Tablets are indicated in the following conditions:

1. **Endocrine Disorders:**
   - Primary or secondary adrenocortical insufficiency (hydrocortisone or cortisone is the first choice; synthetic analogs may be used in conjunction with mineralocorticoids where applicable; in infancy mineralocorticoid supplementation is of particular importance).
   - Congenital adrenal hyperplasia
   - Nonsuppurative thyroiditis
   - Hypercalcemia associated with cancer

2. **Rheumatic Disorders**
   - As adjunctive therapy for short-term administration (to tide the patient over an acute episode or exacerbation) in:
     - Psoriatic arthritis
     - Rheumatoid arthritis, including juvenile rheumatoid arthritis (selected cases may require low-dose maintenance therapy)
     - Ankylosing spondylitis
     - Acute and subacute bursitis
     - Acute gouty arthritis
     - Post-traumatic osteoarthritis
     - Synovitis of osteoarthritic joints
     - Epicondylitis.

3. **Collagen Diseases**
   - During exacerbation or as maintenance therapy in selected cases of:
     - Systemic lupus erythematosus
     - Systemic dermatomyositis (polymyositis)
     - Acute rheumatic carditis

4. **Dermatologic Diseases**
   - Pemphigus
   - Bullous dermatitis herpetiformis
   - Severe erythema multiforme (Stevens-Johnson syndrome)
   - Exfoliative dermatitis
   - Mycosis fungoides
   - Severe pemphigus
   - Severe sarcoidosis dermatis

5. **Allergic States**
   - Control of severe or incapacitating allergic conditions inadaptable to adequate trials of conventional treatment:
     - Seasonal or perennial allergic rhinitis
     - Bronchial asthma
     - Atopic dermatitis
     - Serum sickness
     - Drug hypersensitivity reactions

6. **Ophthalmic Diseases**
   - Severe acute and chronic allergic and inflammatory processes involving the eye and its adnexa such as:
     - Allergic conjunctivitis
     - Herpes zoster ophthalmicus
     - Anterior segment inflammation
     - Diffuse posterior uveitis and chorioiditis
     - Sympathetic ophthalmia
     - Allergic conjunctivitis
     - Keratitis
     - Chorioretinitis
     - Optic neuritis
     - Iritis and iridocyclitis

7. **Respiratory Diseases**
   - Symptomatic sarcoidosis
   - Lou Gehrer’s syndrome not manageable by other means
   - Bronchitis
   - Fulminating or disseminated pulmonary tuberculosis when used concurrently with appropriate antibacterial chemotherapy
   - Aspiration pneumonitis

8. **Hematologic Disorders**
   - Idiopathic thrombocytopenic purpura in adults
   - Secondary thrombocytopenia in adults
   - Acquired (autoimmune) hemolytic anemia
   - Erythroid-stimulating anemia (ESA) in myelodysplastic syndrome
   - Congenital erythropoietic porphyria

9. **Neoplastic Diseases**
   - For palliative management of:
     - Leukemia and lymphomas in adults
     - Acute leukemia of childhood

10. **Gastrointestinal Diseases**
    - To tide the patient over a critical period of the disease in:
      - Ulcerative colitis
      - Regional enteritis

11. **Nervous System**
    - Acute exacerbations of multiple sclerosis

12. **Miscellaneous**
    - Tuberculous meningitis with subarachnoid block or, impending block when used concurrently with appropriate antibacterial chemotherapy
    - Trichinosis with neurologic or myocardial involvement.

**CONTRAINDICATIONS**

Prednisone tablets are contraindicated in systemic fungal infections and known hypersensitivity to components.

**WARNINGS**

In patients on corticosteroid therapy subjected to unusual stress, increased dosage of rapidly acting corticosteroids before, during, and after the stressful situation is indicated. Corticosteroids may mask signs of infection, and new infections may appear during their use. There may be decreased resistance and inability to localise 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.

Usage in pregnancy: Since adequate human reproduction studies have not been done with corticosteroids, the use of these drugs in pregnancy, nursing mothers or women of childbearing potential requires that the possible benefits of the drug be weighed against the potential hazards to the mother and embryo or fetus. Infants born of mothers who have received substantial doses of corticosteroids during pregnancy, should be carefully observed for signs of hypoadrenalism. 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.

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.

The use of prednisone tablets 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 anti-tuberculous regimen. If corticosteroids are indicated in patients with latent tuberculosis or tuberculosis reactivity, close observation is necessary as reactivation of the disease may occur. During prolonged corticosteroid therapy, patients should receive chemoprophylaxis.

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. How the dose, route and duration of the corticosteroid administration affects the risk of developing a disseminated infection is unknown.

The contribution of the underlying disease and/or prior corticosteroid treatment to the risk is also not known. If exposed to chickenpox, prophylaxis with varicella-zoster immune globulin (VZIG) may be considered. If exposed to measles, prophylaxis with immune globulin may be considered. (See the respective package inserts for complete VZIG and IG prescribing information.) If chickenpox develops, treatment with antiviral agents may be considered.

**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 situations 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 pituitary dysfunction. 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. Aspirin should be used cautiously in conjunction with corticosteroids in hypoprothrombinemia. Psychiatric 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 psychiatric tendencies may be aggravated by corticosteroids.

Steroids should be used with caution in non-specific 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 on prolonged corticosteroid therapy should be carefully observed.

Although controlled clinical trials have shown corticosteroids to be effective in speeding the resolution of acute exacerbations of multiple sclerosis, they do not show that corticosteroids affect the ultimate outcome of the disease process in the patient's lifetime; the study results show that relatively high doses of corticosteroids are necessary to demonstrate a significant effect. (See DOSAGE AND ADMINISTRATION.)

Since complications of treatment with glucocorticoids are dependent on the size of the dose and the duration of treatment, a risk/benefit decision must be made in each individual case as to dose and duration of treatment and as to whether daily or intermittent therapy should be used. Convulsions have been reported with concurrent use of methylprednisolone and cyclosporine. Since concurrent use of these agents results in a mutual inhibition of metabolism, it is possible that adverse events associated with the individual use of either drug may be more apt to occur.

Information for the Patient:

Persons 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.

ADVERSE REACTIONS

Fluid and Electrolyte Disturbances: Sodium retention

Fluid retention

Congestive heart failure in susceptible patients

Potassium loss

Hypokalemic alkalosis

Hyponatremia

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

Ulcereative esophagitis

Dermatologic:

Impaired wound healing

Thin fragile skin

Petechiae and ecchymoses

Facial plethora

Increased sweating

May suppress reactions to skin tests

Metabolic:

Negative nitrogen balance due to protein catabolism

Neurological:

Convulsions

Increased intracranial pressure with papilledema (pseudotumor 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 diabetes

Ophthalmic:

Decreased intraocular pressure

Increased intraocular pressure

Glaucoma

Exophthalmos

Additional Reactions:

Urticaria and other allergic, anaphylactic or hypersensitivity reactions.

DOSAGE AND ADMINISTRATION

The initial dosage of prednisone may vary from 5 mg to 60 mg per day 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. If after a reasonable period of time there is a lack of satisfactory clinical response, prednisone should be discontinued and the patient transferred to other appropriate therapy.

It should be emphasized that dosage requirements are variable and must be individualized on the basis of the disease under treatment and the response of the patient.

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's response 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 prednisone for a period of constant duration. If after long-term therapy the drug is to be stopped, it is recommended that it be withdrawn gradually rather than abruptly.

Multiple Sclerosis

In the treatment of acute exacerbations of multiple sclerosis daily doses of 200 mg of prednisone for a week followed by 80 mg every other day for 1 month have been shown to be effective.