

PRESCRIBING INFORMATION

WINPRED® Tablets

Prednisone Tablets USP

1 mg

Glucocorticoid

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DATE OF PREPARATION:
November 7, 2013

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THERAPEUTIC CLASSIFICATION

Glucocorticoid

INDICATIONS AND CLINICAL USE

Prednisone is about 5 times more potent on a weight basis than cortisone in glucocorticoid and anti-inflammatory activity. It has considerably less mineralocorticoid activity than cortisone. Prednisone is used in the management of conditions generally responsive to corticosteroids such as:

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, mineralocorticoids supplementation is of particular importance); congenital adrenal hyperplasia; nonsuppurative thyroiditis; hypercalcemia associated with cancer.

Rheumatic disorders

As adjunctive therapy for short-term administration (to tide the patient over an acute episode or exacerbation) in: psoriatic arthritis, rheumatoid arthritis (selected cases may require low dose maintenance therapy), ankylosing spondylitis, acute and subacute bursitis, acute non-specific tenosynovitis, acute gouty arthritis.

Collagen diseases

During an exacerbation or as maintenance therapy in selected cases of – systemic lupus erythematosus, acute rheumatic carditis, systemic dermatomyositis (polymyositis)

Dermatologic diseases

Pemphigus, bullous dermatitis herpetiformis, severe erythema multiforme (Stevens-Johnson syndrome), exfoliative dermatitis, mycosis fungoides, severe psoriasis.

Allergic states

Control of severe or incapacitating allergic conditions intractable to adequate trials of conventional treatment such as seasonal or perennial allergic rhinitis, bronchial asthma, contact dermatitis, atopic dermatitis, serum sickness, angioedema and urticaria.

Ophthalmic disease

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 (but **not** herpes simplex), iritis and iridocyclitis, chorioretinitis, anterior segment inflammation, diffuse posterior uveitis and choroiditis, optic neuritis, retrobulbar neuritis, sympathetic ophthalmia.

Respiratory diseases

Symptomatic sarcoidosis, Loeffler's syndrome not manageable by other means, berylliosis, fulminating or disseminated pulmonary tuberculosis when concurrently accompanied by appropriate antituberculous chemotherapy, pulmonary emphysema where bronchospasm or bronchial edema plays a significant role, diffuse interstitial pulmonary Fibrosis (Hamman-Rich syndrome).

Hematologic disorders

Idiopathic and secondary thrombocytopenia in adults, acquired (autoimmune) hemolytic anemia, erythroblastopenia (RBC anemia), congenital (erythroid) hypoplastic anemia.

Neoplastic diseases

For palliative management of leukemias and lymphomas in adults, acute leukemia of childhood.

Renal diseases

To induce a remission of proteinuria in the nephrotic syndrome, without uremia, of the idiopathic type or that due to lupus erythematosus. In conjunctions with diuretic agents, to induce a diuresis in cirrhosis of the liver with refractory ascites, refractory congestive heart failure.

Gastrointestinal diseases

To tide the patient over a critical period of the disease in ulcerative colitis, regional enteritis, intractable sprue.

Miscellaneous

Tuberculous meningitis with subarachnoid block or impending block when concurrently accompanied by appropriate antituberculous chemotherapy, dental postoperative inflammatory reactions.

CONTRAINDICATIONS

Systemic fungal infections.

PRECAUTIONS

In patients on corticosteroid therapy subjected to unusual stress, increased dosage of rapidly acting corticosteroids before, during, and after the stressful situation is indicated.

Restrict the use of prednisone in active tuberculosis to those cases of fulminating 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.

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. If corticosteroids have to be used in the presence of bacterial infections, institute appropriate anti-infective therapy.

Use corticosteroids cautiously in patients with ocular herpes simplex because of possible corneal ulceration and perforation.

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.

Use the lowest possible corticosteroid dose to control the condition under treatment.

Average and large doses of hydrocortisone or cortisone can cause elevation of blood pressure, salt and water retention, and increased potassium excretion. 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.

Drug induced secondary adrenocortical insufficiency may be minimized by gradual dosage reduction. This type of relative insufficiency may persist for months after discontinuation of therapy; therefore, in any stress situation occurring during that period, reinstitute hormone therapy. If the patient is receiving corticosteroids already, the dosage may have to be increased. Since mineralocorticoid secretion may be impaired, salt and/or a mineralocorticoid should be administered concurrently.

Use corticosteroids 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 and osteoporosis. Fat embolism has been reported as a possible complication of the hypercortisonism.

When used in myasthenia gravis, hospitalization with careful observation is recommended because a transient worsening of symptoms possibly leading to respiratory distress may precede clinical improvement.

There is an enhanced effect of corticosteroids on patients with hypothyroidism and in those with cirrhosis.

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.

Corticosteroids may increase or decrease motility and number of spermatozoa in some patients.

Advise patients to inform subsequent physicians and dentists of the prior use of corticosteroids.

Drug interactions

Patients receiving immunosuppressive doses of corticosteroids should not be vaccinated with live vaccines due to the risk of developing the viral disease. Other immunizations are not recommended due to an increased risk of neurologic disease and poor antibody response. Large doses inhibit the positive reaction to tuberculin or histoplasmin skin tests and patch tests for allergy.

Corticosteroids increase clearance of ASA and decrease effectiveness of anticoagulants; dosage adjustment may be necessary. Corticosteroids may increase glucose and require higher doses of insulin or oral hypoglycemics. Potassium should be monitored closely especially when given with other drugs that decrease potassium such as loop diuretics and amphotericin.

Phenytoin, barbiturates and rifampin may enhance the rate of metabolism and clearance of corticosteroids, and this may increase corticosteroid dosage requirements.

Pregnancy and Lactation

Since adequate human reproduction studies have not been done with corticosteroids, the use of these drugs in pregnancy, nursing mothers or women of children bearing potential requires that the drug's possible benefits 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.

Children

Growth and development of infants and children on prolonged corticosteroid therapy should be carefully observed.

ADVERSE REACTIONS

Fluid and electrolyte disturbances: sodium retention; fluid retention; congestive heart failure in susceptible patients; potassium loss; hypokalemic alkalosis; hypertension; hypocalcemia.

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); 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.

Psychologic: hallucinations, mood changes, psychosis.

Ophthalmic: posterior subcapsular cataracts; increased intraocular pressure; glaucoma; exophthalmos; enhanced possibility of a viral or fungal infection.

Metabolic: negative nitrogen balance due to protein catabolism.

Other: hypersensitivity, thromboembolism, hypercholesterolemia, accelerated atherosclerosis.

The following additional adverse reactions are related to parenteral corticosteroid therapy: rare instances of blindness associated with intralesional therapy around the face and head; hyperpigmentation or hypopigmentation; subcutaneous and cutaneous atrophy; sterile abscess; postinjection flare (following intra-articular use); Charcot-like arthropathy.

DOSAGE AND ADMINISTRATION

Administration is governed by the following general principles:

Individualize dosage according to the severity of the disease and the patient's response. The severity, prognosis, expected duration of the disease, and the patient's reaction to medication are primary factors in determining dosage. For infants and children, the recommended dosage should be governed by the same considerations rather than by 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 to avoid the risk of relative adrenal insufficiency.

Continued supervision of the patient after cessation of corticosteroids is essential, since there may be a reappearance of severe manifestations of the disease for which the patient was treated.

In acute conditions where prompt relief is imperative, large doses are permissible and may be mandatory for a short period.

In chronic conditions requiring long-term therapy, use the lowest dosage that provides adequate, but not necessarily complete relief. If a high dosage for prolonged periods is considered essential, observe patients closely for signs that might necessitate reduction in dosage or discontinuance of the hormone.

Prednisone may be administered as a single morning dose on alternate days in patients with a normal or moderately responsive pituitary axis on long-term corticosteroid therapy. This regimen is designed to minimize hypothalamic-pituitary-adrenal suppression.

Chronic conditions are subject to periods of spontaneous remission. When such periods occur, discontinue corticosteroids gradually.

The following milligram equivalents facilitate changing to prednisone from other glucocorticoids:

TABLE 1

Duration and Drug	Equivalent Anti-inflammatory Dose (mg)
<i>Short-acting (biologic activity 8-12 h)</i>	
Cortisone	25
Hydrocortisone	20
<i>Intermediate-acting (biologic activity 12-36 h)</i>	
Methylprednisolone	4
Prednisolone	5
Prednisone	5
Triamcinolone	4
<i>Long-acting (biologic activity 36-54 h)</i>	
Betamethasone	0.6
Dexamethasone	0.75

Specific dosage recommendations for prednisone in chronic, usually nonfatal diseases, including endocrine and chronic rheumatic disorders, edematous states, respiratory and gastrointestinal diseases, some dermatologic diseases and hematologic disorders, start with a low dose (5 to 10 mg/day) and gradually increase dosage to the smallest amount that gives the desired degree of symptomatic relief. When adequate suppression of symptoms is achieved, maintain dosage at the minimum amount capable of providing sufficient relief without excessive hormonal effects.

In congenital adrenal hyperplasia, the usual daily dose is 2.5 to 10 mg.

In acute nonfatal disease, including allergic states, ophthalmic disease, acute and subacute rheumatic disorders, dosage ranges between 20 and 30 mg a day. In some patients higher doses are necessary. Since these conditions are self-limited in their course, prolonged maintenance therapy is not usually necessary.

In chronic potentially fatal diseases such as systemic lupus erythematosus, pemphigus, symptomatic sarcoidosis, the initial dosage is 30 mg a day. In some patients, higher doses are necessary. As soon as adequate relief is obtained, reduce dosage gradually to the minimum amount that will produce the desired therapeutic effect.

When the disease is acute and life threatening (e.g, acute rheumatic carditis, crisis of systemic lupus erythematosus, severe allergic reactions, pemphigus, neoplastic diseases), the initial dosage is 30 mg a day, administered in 4 divided doses. This dosage may have to be increased in some patients to establish control. As soon as control is attained, reduce dosage gradually to the minimum amount that will maintain relief. When extremely rapid onset of action is desired, one of the soluble adrenocortical hormone preparations may be administered i.v. for the first 2 or 3 doses. In severe allergic reactions, epinephrine is the drug of immediate choice.

Prednisone is useful either concurrently or as supplementary therapy.

In certain conditions, such as acute leukemia, and nephrotic syndrome, the recommended dosage is 30 mg a day, or more.

In dental postoperative inflammatory reactions, administer 5 mg 3 times a day, for no more than 2 or 3 days.

AVAILABILITY OF DOSAGE FORMS

1 mg: Each round, white, flat-faced with bevelled edge tablet, engraved ICN on one side and W1 on the other side, contains prednisone 1 mg. Available in bottles of 100.