4. Dermatologic Diseases
2. Rheumatic Disorders
1. Endocrine Disorders

INDICATIONS

Glucocorticoids cause profound and varied metabolic effects. In addition, they modify the body's immune responses to diverse stimuli. Glucocorticoids are adrenocortical steroids, both naturally occurring and synthetic, which are mostly absorbed from the gastrointestinal tract. Glucocorticoids cause profound and varied metabolic effects. In addition, they modify the body's immune responses to diverse stimuli.

Glucocorticoids are analogs of the naturally occurring glucocorticoids and are used as replacement therapy in adrenocortical deficiency states. Their synthetic analogs are primarily used for their potent anti-inflammatory effects in disorders of many organ systems.

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Prednisone Tablets, USP 10 mg contains FD & C yellow #6, aluminum lake, HT 15-18%, Pregelatinized Starch, Sodium Lauryl Sulfate and Sodium Starch Glycolate. Also Prednisone Tablets, USP 20 mg contains FD & C yellow #6, aluminum lake, HT 15-18%.

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the ultimate outcome or natural history of the disease. The studies do 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 will be used.

Conclusions 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 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
Hypokalemia alkalosis
Hypertension
Musculoskeletal
Muscle weakness
Stercoraralmythosis
Loss of muscle mass
Osteoporosis
Osteoporosis
Venous thrombosis fractures
Aseptic necrosis of femoral and humeral heads
Pathologic fracture of long bones
Gastrointestinal
Peptic ulcer with possible perforation and hemorrhage
Pericarditis
Adenopathy
Abdominal distension
Ulcerative esophagitis
Dermatologic
Impaired wound healing
Thin fragile skin
Petechiae and ecchymoses
Facial edema
Increased sweating
May suppress reactions to skin tests
Metabolic
Negative nitrogen balance due to protein catabolism
Neurological
Increased intracranial pressure with papilledema (pseudotumor cerebri) usually after treatment
Convulsions
Vertigo
Headache
Endocrine
Minimal irregularities
Development of Cushingoid state
Secondary adrenocortical and pituitary unresponsiveness, particularly in times of stress, as in trauma, surgery or illness
Suppression of growth in children
Decreased carbohydrate tolerance
Manifestations of latent diabetes mellitus
Increased requirements for insulin or oral hypoglycemic agents in diabetes
Ophtalmologic
Posterior subcapsular cataracts
Increased intracocular pressure
Glaucoma
Exophthalmos
Additional Reactions
Urticaria and other allergic, anaphylactic or hypersensitivity reactions.

DOSAGE AND ADMINISTRATION

The initial dosage of Prednisone Tablets, USP may vary from 5 mg to 60 mg of prednisone 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.

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 prednisone 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.

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. (Dosage range is the same for prednisone and prednisolone.)

ADT® (Alternate Day Therapy)

ADT is a corticosteroid dosing regimen in which twice the usual daily dose of corticoid is administered every other morning. The purpose of this mode of therapy is to provide the patient requiring long-term pharmacologic dose treatment with the beneficial effects of corticoids while minimizing certain undesirable effects, including pituitary-adrenal suppression, the Cushingoid state, corticoid withdrawal symptoms, and growth suppression in children. The rationale for this treatment schedule is based on two major premises: (a) the anti-inflammatory or therapeutic effect of corticoids persists longer than their physical presence and metabolic effects and (b) administration of the corticosteroid every other morning allows for re-establishment of more nearly normal hypothalamic-pituitary-adrenal (HPA) activity on the off-steroid day.

A brief review of the HPA physiology may be helpful in understanding this rationale. Acting through the hypothalamus, a daily therapeutic dose of prednisone inhibits the pituitary gland to produce increasing amounts of corticotropin (ACTH) while a rise in free cortisol inhibits ACTH secretion. Normally the HPA system is characterized by diurnal circadian rhythms, where peak levels of ACTH rise from a low point about 10 pm to a peak level about 6 am. Increasing levels of ACTH stimulate adrenocortical activity resulting in a rise in plasma cortisol with maximal levels occurring between 2 am and 8 am. This rise in cortisol dampens ACTH production and in turn adrenocortical activity. There is a gradual fall in plasma corticoids during the day with lowest levels occurring about midnight. The diurnal rhythm of the HPA axis is lost in Cushing’s disease, a syndrome of adrenocortical hyperfunction characterized by centrally neurally fat distribution, thinning of the skin with easy bruability, muscle wasting with weakness, hypertension, latent diabetes, osteoporosis, electrolyte imbalance, etc. The same clinical findings of hyperadrenocorticism may be noted during long-term pharmacologic dose corticoid therapy administered in conventional daily dosages. It would appear, then, that a disturbance in the diurnal cycle with maintenance of elevated corticoid values during the night may play a significant role in the development of undesirable corticoid effects. Escape from these constantly elevated plasma levels for even short periods of time may be instrumental in preventing against undesirable pharmacologic effects. During conventional pharmacologic dose corticosteroid therapy, ACTH production is inhibited with subsequent suppression of cortisol production by the adrenal cortex. Recovery time for normal HPA activity is variable depending upon the dose and duration of treatment. During this time the patient is vulnerable to any stress and it may be beneficial to lower the dosage of corticoids by fractional amounts or reduce the 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 prednisone 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.