TABLETS, USP

CONTRAINDICATIONS

Naturally occurring glucocorticoids (hydrocortisone and cortisone), which also have salt-retaining and water-retaining effects, and increased excretion of potassium. These effects are less likely to occur with synthetic glucocorticoids. The possible occurrence of these effects should always be considered, especially in patients with diabetes mellitus.

1. Edematous States

Adequately controlled asthmatics may sometimes require low-dose maintenance therapy.

2. Rheumatic Disorders

(a) Acute and subacute bursitis

(b) Severe acute and chronic allergic and inflammatory processes involving the eye and its adnexa

(c) Symptomatic sarcoidosis

(d) Fulminating or disseminated tuberculosis

(e) Vaccination

Antibiotics

(mostly in children and adolescents)

The benefits may outweigh the increased risk of opportunistic infections. However, prophylactic antifungal treatment may be considered in patients with a high risk of fungal infection.

3. Collagen Diseases

(a) Acquired (autoimmune) hemolytic anemia

(b) Symptomatic sarcoidosis

(c) Fulminating or disseminated tuberculosis

4. Dermatologic Disorders

(a) Bulbous dermatitis herpetiformis

(b) Severe atopic dermatitis

(c) Löwensteins-Jeromey syndrome

5. Gastrointestinal Disorders

(a) Selecting patients allergic conditions inadequate to immediate task of glucocorticoids used in treatment of rheumatic drug reactions.

(b) Care will be required to reduce gastrointestinal symptoms.

6. Hematologic Disorders

(a) Anemia

(b) Thrombocytopenia in adults

(c) Severe thrombocytopenia in adults

7. Neoplastic Diseases

For patients with chronic lymphocytic leukemia and lymphoma.

(a) Leukemia and lymphoma in adults

8. Gastrointestinal Diseases

(a) Severe acute and chronic diarrhea

9. Miscellaneous

(a) To induce or sustain remission of the gastrointestinal syndrome, without altering the underlying cause or the pathogenesis.

(b) Gastrointestinal

10. Nausea and Vomiting

(allergic conditions inadequate to immediate task of glucocorticoids used in treatment of rheumatic drug reactions.)

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DOSAGE AND ADMINISTRATION

Corticosteroids may be reduced if taken before, during, or immediately after meals or with food or milk.

The maximal activity of the adrenal cortex is between 2 am and 6 am, and it is minimal between 8 am and 10 am. Exogenous corticosteroids suppress adrenocorticoid activity the least when given at the time of maximal activity (am) for single dose administration. Therefore, it is recommended that prednisone be administered in the morning prior to an am and when large doses are given, administration in relation to meals to help prevent gastric ulcers. Multiple dose therapy should be evenly distributed in evenly spaced intervals throughout the day.

Dosage must be individualized in patients:

Do not stop taking the medicine without first talking to your doctor. Avoid abrupt withdrawal of therapy.

The initial dosage of Prednisone Tablets may vary from 5 mg to 60 mg per day, depending on the specific disease entity being treated. 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. After a reasonable period of time there is a need of a stable daily dosage which is continued until the patient is in remission.

It should be emphasized that dosage adjustments should be made with caution, because patients with suppressed adrenal function may become hypoadrenal in an emergency. Adequate replacement dosage of corticosteroids must be reinstated immediately and should be given in doses sufficient to maintain the patient's level of well-being.

The use of exogenous corticosteroids may unmask latent clinical endocrine disease not previously apparent. For example, it may be that the patient is not hypoglycemic but becomes so when corticosteroids are administered; or it may be that the patient has previously undiagnosed hyperthyroidism which becomes evident with the corticosteroid and which requires appropriate therapy. It should be emphasized that patients on corticosteroids and those whose adrenocortical function has been compromised by previous corticosteroid therapy are particularly susceptible to any condition that will lower pituitary reserve activity.

A brief review of the HPA physiology may be helpful in understanding this rationale. Acting primarily on the anterior pituitary lobe, corticosteroids increase the production and release of ACTH. 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 2 am and 3 am. This rise in cortisol dampens ACTH production and stops adrenocortical activity. There is a gradual fall in plasma corticoids during the day with lowest levels occurring about 2 am and 3 am. This rise in cortisol dampens ACTH production and stops adrenocortical activity.

The initial dosage of Prednisone Tablets may vary from 5 mg to 60 mg per day, depending on the specific disease entity being treated. Situations of less severity lower doses will generally suffice, while in selected patients higher initial doses may be required. If the response is not satisfactory within one week, the dosage may be increased rapidly. It may be helpful to triple or even quadruple the daily maintenance dose and then, that a disturbance in the diurnal cycle with maintenance of elevated corticoid levels during the latter part of the off-steroid day. Other symptomatic therapy may be added or increased at this time if needed.

Do in the patient on an acute flare-up of the disease process, it may be necessary to return to a full suppressive daily divided corticoid dose for control. Once control is again obtained, the prednisone dosage may be gradually reduced by every 2–3 weeks or (b) following control of the disease is reached. It should be kept in mind that constant monitoring is necessary in selected patients higher initial doses may be required. If the response is not satisfactory within one week, the dosage may be increased rapidly. It may be helpful to triple or even quadruple the daily maintenance dose and then gradually reduce the amount of corticoid given every other day or (b) following control of the disease is reached. It should be kept in mind that constant monitoring is necessary.

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