tendecies 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 peritoneal 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.

ADVERSE REACTIONS

Fluid and Electrolyte Disturbances
- Sodium retention
- Fluid retention
- Congestive heart failure in susceptible patients
- Potassium loss
- Hypokalemia; alkalosis

Musculoskeletal
- Muscle weakness
- Stiffness
- Loss of muscle mass
- Osteoporosis
- Vertebral compression fractures
- Aspiration or tearing 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 (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
- Posterior subcapsular cataracts
- Increased intraocular pressure
- Glaucoma
- Exophthalmos

Metabolic
- Negative nitrogen balance due to protein catabolism

DOSE AND ADMINISTRATION

Dosage of Prednisolone Syrup (Prednisolone Oral Solution USP) 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.

Hormone therapy is an adjunct to and not a replacement for conventional therapy.

Dosage should be decreased or discontinued gradually when the drug has been administered for more than a few days.

The severity, prognosis, expected duration of the disease, and the reaction of the patient to medication are primary factors in determining dosage. If a period of spontaneous remission occurs in a chronic condition, treatment should be discontinued.

Blood pressure, body weight, routine laboratory studies, including two-hour postprandial blood glucose and serum potassium, and a chest X-ray should be obtained at regular intervals during prolonged therapy. Upper GI X-rays are desirable in patients with known or suspected peptic ulcer disease.

The initial dosage of Prednisolone Syrup (Prednisolone Oral Solution USP) 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, Prednisolone Syrup (Prednisolone Oral Solution USP) 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 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 Prednisolone Syrup (Prednisolone Oral Solution USP) 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.

HOW SUPPLIED

Prednisolone Syrup (Prednisolone Oral Solution USP) is a cherry flavored red liquid containing 15 mg of prednisolone in each 5 mL (teaspoonful) and is supplied in 240 mL and 480 mL bottles.

Pharmacist: Dispense with a suitable calibrated measuring device to assure proper measuring of dose.

DOSE/VOLUME CHART
- 15 mg prednisolone = 1 teaspoon
- 10 mg prednisolone = 2 1/2 teaspoons
- 7.5 mg prednisolone = 1/2 teaspoon
- 5 mg prednisolone = 1/3 teaspoon

Dispense in tight, light-resistant and child-resistant containers as defined in the USP.

Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature]. Do Not Refrigerate.

Manufactured for:
QUALITEST PHARMACEUTICALS
Huntsville, AL 35811

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