PREDNISOLONE SYRUP, USP
15 mg/5mL

DESCRIPTION
Prednisolone Syrup contains Prednisolone, which is a glucocorticoid. Glucocorticoids are adrenocortical steroids, both naturally occurring and synthetic, which are readily absorbed from the gastrointestinal tract. Prednisolone is a white to practically white, odorless crystalline powder. It is very slightly soluble in water, slightly soluble in alcohol, as chloroform, in ethylene, and in methylene.

The chemical name for Prednisolone is 11B, 17a-Dihydroxy-17-N-methylpregna-1, 4-diene-3, 20-dione (5a). The molecular formula is C21H26O3, and the structural formula is:

Prednisolone Syrup contains 15 mg of Prednisolone in each 5 mL. It also contains inactive ingredients: Alcohol, Benzyl Alcohol, Caramel Color, Citric Acid, Sodium Citrate, FD&C Red No. 40, Flavors, Glycerin, Propylene Glycol, Purified Water, Sodium Saccharin, & Sorbic Acid.

CLINICAL PHARMACOLOGY
Naturally occurring glucocorticoids (hydrocortisone and cortisone), which also have salt-retaining properties, are used as replacement therapy in adrenocortical deficiency states. Their synthetic analogs such as prednisolone cause profound and varied metabolic effects. In addition, they modify the body’s immune responses to diverse stimuli.

INDICATIONS AND USAGE
Prednisolone Syrup is indicated in the following conditions:

1. Carcinoid Diarrhea
   - Primary or secondary adrenocortical insufficiency (hydrocortisone or cortisone is the first choice; synthetic analogs may be used in conjunction with mineralocorticoids where applicable; in primary adrenocortical insufficiency is of particular importance.)
   - Congestive heart failure
   - Adrenal insufficiency associated with surgery

2. Rheumatic Disorders
   - An adjuvant therapy for short-term treatment (to tide the patient over an acute episode or exacerbation) in:
     - Prolonged use of nonsteroidal anti-inflammatory drugs
     - Arthritis, including juvenile rheumatoid arthritis (selected cases may require low-dose maintenance therapy)

3. Colitis Diarrhea
   - During an exacerbation or as maintenance therapy in selected cases of:
     - Systemic lupus erythematosus

4. Dermatologic Diseases
   - Perforating collagenolytic dermatosis
   - Benign dermatitis herpetiformis
   - Severe erythema multiforme (Stevens-Johnson syndrome)
   - Exfoliative dermatitis
   - Mycosis fungoides
   - Severe psoriasis
   - Severe atop dermatitis

5. Allergic States
   - Control of severe or incapacitating allergic conditions intractable to adequate trials of conventional treatment:
     - Seasonal or perennial allergic rhinitis
     - Bronchial asthma
     - Contact dermatitis
     - Nummular dermatitis

6. Ophthalmic Diseases
   - Severe acute and chronic allergic inflammatory processes involving the eye and its adnexa such as:
     - Allergic conjunctivitis
     - Neoplasms of the orbit or lid

7. Respiratory Diseases
   - Bronchial asthma
   - Acute exacerbation of bronchitis
   - Acute exacerbation of chronic bronchitis

8. Hematologic Disorders
   - Idiopathic thrombocytopenic purpura in adults
   - Secondary thrombocytopenia in adults
   - Acquired (autoimmune) hemolytic anemia
   - Cryoglobulinemia (RBC anemia)

9. Renal Disease
   - For palliative management of:
     - Eclampsia
     - Hypertensive crisis

10. Endocrine Disorders
    - To induce a diabetes or remission of diabetes mellitus in patients unresponsive to insulin therapy

11. Dermatologic Diseases
    - To tide the patient over a crisis period of the disease in:
      - Seborrheic dermatitis
      - Regional enteritis

12. Miscellaneous
    - Tuberculosis meningitis with satisfactory control of infection in normal volunteers
    - Malignant neoplasms with satisfactory control of malignant growth in patients not responding to more adequate therapy

CONTRAINdications
Systemic fungal infections.

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

Corticosteroids may cause some signs of infection, and new infections may appear during their use.

Prolonged use of corticosteroids may produce postural hypotension, cardiac arrhythmias, hyperglycemia with possible damage to the optic nerves, and may enhance the establishment of secondary ocular injuries due to fungi or viruses.

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 synthetic derivatives except when used in large doses. Dietary salt restrictions and potassium supplementation may be necessary. All corticosteroids increase calcium excretion.

While on corticosteroids 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.

Persons who are on drugs which suppress the immune system are more susceptible to infections than healthy individuals. Cushingoid and meatballs, 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 corticosteroid administration, the risk of developing a disseminated infection is not known.

If exposed to chickenpox, prophylaxis with varicella zoster immune globulin (VZIG) may be indicated (see the respective package inserts for complete VZIG and VIG prescribing information).
PRECAUTIONS

GENERAL
Drug-induced secondary anorexia/insufficiency may be minimized by gradual reduction of dosage. This type of relative insufficiency may persist for months after discontinuation of therapy, therefore, in any situation of stress occurring during that period, hormone therapy should be reinstated. Since mental or neurological sequelae may be impaired, salt and/or a mineralocorticoid should be administered concurrently. There is an enhanced effect of corticosteroids on patients with hyperthyroidism and in those with herpes. Corticosteroids should be used cautiously in patients with septic herpes simplex because of possible increased infection.

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. Psychiatric disturbances may appear when corticosteroids are used, ranging from euphoria, insomnia, mood swings, personality changes and severe depression, to frank psychotic manifestations. Also, existing emotional lability or psychiatric tendencies may be aggravated by corticosteroids.

Adequate should be used cautiously in conjunction with corticosteroids in hypertensive patients.

Steroids should be used with caution in nonprone orthopedic surgery, if there is a probability of impending perforation, obstruction or other gastric/duodenal, biliary or pancreatic lesions, and in ulcerative or toxic jejunitis. Gastric ulcer and/or gastrointestinal bleeding may occur and even develop initially in patients treated with corticosteroids. There is an increased risk of gastrointestinal complications in the elderly, but even patients as young as 50 years have been reported to have complications from corticosteroids.

Information for patients: Patients who are anorexic or dehydrated should be warned to avoid exposure to infections or injuries. Patients should also be advised that if they are exposed, medical advice should be sought without delay.

ADVERSE REACTION

Fluid and Electrolyte Disturbances
Sodium retention
Fluid retention
Congestive heart failure in susceptible patients
Potassium loss
Hypercalcemia
Hyperkalemia
Hyperglycemia
Hyperuricemia
Muscle weakness
Steroid myopathy
Loss of muscle mass
Osteoporosis
Vertebral compression fractures
Aseptic necrosis of the femoral head
Pathologic fracture of long bones
Gastrointestinal
Peptic ulcer with possible perforation and hemorrhage
Pancreatitis
Abdominal distention
Ulcerative enteropathy
Dermatologic
Imperative wound healing
Thin hair, skin and nails
Pallor and ecchymoses
Skin rashes
Increased sweating
May suppress responses to skin test
Neurological
Convulsions
Increased intraocular pressure with papilledema
(From Medical Letter, 1973; 15:29)

DOSAGE AND ADMINISTRATION

Dosage of Prednisolone Syrup 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 to be continued 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 urinalysis, 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 may vary from 5.0 mg to 60.0 mg per day depending on the specific disease entity being treated. In situations of less severely known 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 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; the dosage of Prednisolone Syrup 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 is a clear, colorless, cherry-flavored liquid containing 15 mg of Prednisolone in each 5 ml (teaspoonful) and is supplied in an 8 oz. (238 mL) and 16 oz. (473 mL) bottles.

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

Dosage/Volume Chart

| 15 mg Prednisolone = 1 teaspoonful |
| 10 mg Prednisolone = 0.7 teaspoonful |
| 7.5 mg Prednisolone = 0.5 teaspoonful |
| 5.0 mg Prednisolone = 0.3 teaspoonful |

Dispense in a tight, light-resistant container with a child-resistant closure.

Store at controlled room temperature 15° - 30° (59° - 86°F).

Do Not Refrigerate.

Rx Only

Manufactured by:
HALSTEY DRUG CO., INC.
Brooklyn, NY 11231-5059 U.S.A.

Rev 2/99

M.B
USUAL DOSAGE:
See package insert.

Dispense in a tight, light-resistant container with a child-resistant closure.

NDC 0879-0801-16

Each teaspoonful (5mL) contains:
Prednisolone USP 15 mg
Alcohol .................. 5%

Store at controlled room temperature,
15°-30°C (59°-86°F).
DO NOT REFRIGERATE

PREDNISOLONE SYRUP, USP

15 mg per 5 mL

Rx Only

16 fl oz (473 mL)

HALSEY DRUG CO., INC.
Brooklyn, NY 11233 U.S.A.

HALSEY
PREDNISOLONE SYRUP, USP

15 mg per 5 mL

Rx Only

8 fl oz (236 mL)

HALSEY DRUG CO., INC.
Brooklyn, NY 11233 U.S.A.