Prednisone is a white to practically white, odorless, crystalline powder and has a molecular weight of 358.44. It melts at about 230°C with some solubility in alcohol, chloroform, dioxane, and methanol. Each tablet, for oral administration, contains 5 mg or 10 mg of prednisone.

Inactive ingredients:
- 5 mg: anhydrous lactose, colloidal silicon dioxide, magnesium stearate, microcrystalline cellulose, sodium starch glycolate, and talc.
- 10 mg: anhydrous lactose, colloidal silicon dioxide, magnesium stearate, microcrystalline cellulose, sodium starch glycolate, and talc.

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 prednisone, are primarily used for their potent anti-inflammatory effects in disorders of many organ systems. Glucocorticoids, such as prednisone, cause profound and varied metabolic effects. In addition, they modify the body’s immune response to diverse stimuli.

INDICATIONS AND USAGE: Prednisone tablets are indicated in the following conditions:
- Endocrine disorders:
  - Nonsuppurative thyroiditis
  - Rheumatic disorders:
    - Acute nonspecific tenosynovitis
    - Epicondylitis
    - Post-traumatic osteoarthritis
    - Acute leukemia of childhood
    - Bullous dermatitis herpetiformis
    - Complications of tuberculosis
    - Cushing’s syndrome
    - Pemphigus
    - Pemphigoid gestationis
    - Severe seborrheic dermatitis
    - Acute and chronic graft-versus-host disease
    - Herpes zoster ophthalmicus
    - Conjunctival edema
- Gastrointestinal diseases:
  - Crohn’s disease
  - Regional enteritis
  - Pernicious anemia
- Collagen diseases:
  - Acne vulgaris
  - Benign recurrent ulcerative keratitis
  - Bullous pemphigoid
  - Drug-induced, secondary adrenocortical insufficiency
  - Hypersensitivity reactions
  - Myasthenia gravis
- Drug Interactions
  - Concurrent use of corticosteroids and cytotoxic agents
  - Corticosteroids and immunosuppressants
- Dermatologic diseases:
  - Acne rosacea
  - Atopic dermatitis
- Ophthalmic diseases:
  - Keratitis
  - Allergic conjunctivitis

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.

Persons who are on drugs which suppress the immune system are more susceptible to infections than healthy individuals. Chickenpox and measles, 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 diseases, particular care should be taken to avoid exposure. How the dose, route and duration of corticosteroid administration affects the risk of developing a disseminated infection is not known. The contribution of the underlying disease and/or prior corticosteroid treatment to the risk is also not known. If exposed to chickenpox, treatment with varicella zoster immune globulin (VZIG) may be indicated. If exposed to measles, prophylaxis with pooled intramuscular immunoglobulin (IG) may be indicated. (See the respective package inserts for complete VZIG and IG prescribing information.) If chickenpox develops, treatment with antiviral agents may be considered.

Similarly, corticosteroids should be used with great care in patients with known or suspected Strongyloides (threadworm) infestation. In such patients, corticosteroid-induced immunosuppression may lead to Strongyloides hyperinfection and dissemination with widespread larval migration, often accompanied by severe enterocolitis and potentially fatal gram-negative septicemia.

PRECAUTIONS: General: Drug-induced, secondary adrenocortical 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 mineralocorticoid secretion may be impaired, salt and/or a mineralocorticoid should be administered concurrently.

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

Corticosteroids should be used cautiously in patients with ocular herpes simplex because of possible corneal perforation.

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.

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. Corticosteroids should be used with caution in nonspecific ulcerative colitis, if there is a probability of impending perforation, abscess or other pathogen 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.

Kaposi’s sarcoma has been reported to occur in patients receiving corticosteroid therapy. Discontinuation of corticosteroids may result in clinical remission.

Although controlled clinical trials have shown corticosteroids to be effective in speeding the resolution of acute exacerbations of multiple sclerosis, they do not show that corticosteroids affect 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 should be used.

Convulsions have been reported with concurrent use of methylprednisolone and cyclophosphamide. Since convulsions may occur as a result 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.

Drug Interactions
The pharmacokinetic interactions listed below are potentially clinically important. Drugs that induce hepatic enzymes such as phenobarbital, phenytoin and rifampin may increase the clearance of corticosteroids and may require increases in corticosteroid dose to achieve the desired response. Drugs such as troglitazone and ketoconazole may inhibit the metabolism of corticosteroids and thus decrease their clearance. Therefore, the dose of corticosteroid should be titrated to avoid steroid toxicity. Corticosteroids may increase the clearance of chronic high dose aspirin. This could lead to decreased salicylate serum levels and increase the risk of salicylate toxicity when corticosteroid is withdrawn. Aspirin should be used cautiously in conjunction with corticosteroids in patients suffering from hypoglycemia. The effect of corticosteroids on oral anticoagulants is variable. There are reports of enhanced as well as diminished effects of anticoagulants when given concurrently with corticosteroids. Therefore, coagulation indices should be monitored to maintain the desired anticoagulant effect.
Information for Patients: Persons 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 expected 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
Hypertension
Musculoskeletal:
Muscle weakness
Steroid myopathy
Loss of muscle mass
Osteoporosis
Tendon rupture, particularly of the Achilles tendon
Vertebral compression fractures
Gastrointestinal:
Peptic ulcer with possible perforation and hemorrhage
Pancreatitis
Vertebral compression fractures
Hormone therapy is an adjunct to, and not a replacement for,
this rationale. Acting primarily through the hypothalamus a fall in
free cortisol stimulates the pituitary gland to produce increasing
amounts of corticotropin (ACTH) while a rise in free cortisol inhibits
other morning allows for re-establishment of more nearly normal
VARIABLE AND MUST BE INDIVIDUALIZED ON THE BASIS OF THE
situation. Although it has been shown that there is considerably
anterior and allergic, anaphylactic or hypersensitivity reactions
To report SUSPECTED ADVERSE REACTIONS, contact Perrigo
1 Fekety R. Infections associated with corticosteroids and
8) In the event of an acute flare-up of the disease process, it may be
9) Although many of the undesirable features of corticosteroid therapy
can be minimized by ADT, as in any therapeutic situation, the
physician must carefully weigh the benefit-risk ratio for each patient
in whom corticosteroid therapy is being considered.

HOW SUPPLIED:
Prednisone Tablets, USP 5 mg: White, Round Tablets; Debossed
“West-ward 475” on one side and Scored on the other side. Each
tablet contains 5 mg of prednisone for oral administration.
Blister Pack of 21 tablets NDC# 45802-733-21
Blister Pack of 48 tablets NDC# 45802-733-67
Prednisone Tablets, USP 10 mg: White, Round Tablets; Debossed
“WEST-WARD 473” on one side and Scored on the other side. Each
tablet contains 10 mg of prednisone for oral administration.
Blister Pack of 21 tablets NDC# 45802-383-21
Blister Pack of 48 tablets NDC# 45802-383-67

Manufactured by: West-ward Pharmaceutical Corporation, Eatontown, NJ 07724
Contributed By: Perrigo

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2 Stuck AE, Minder CE, Frey FJ. Risk of infectious complications in patients