PREDNISOLONE- prednisolone solution
RedPharm Drug, Inc.

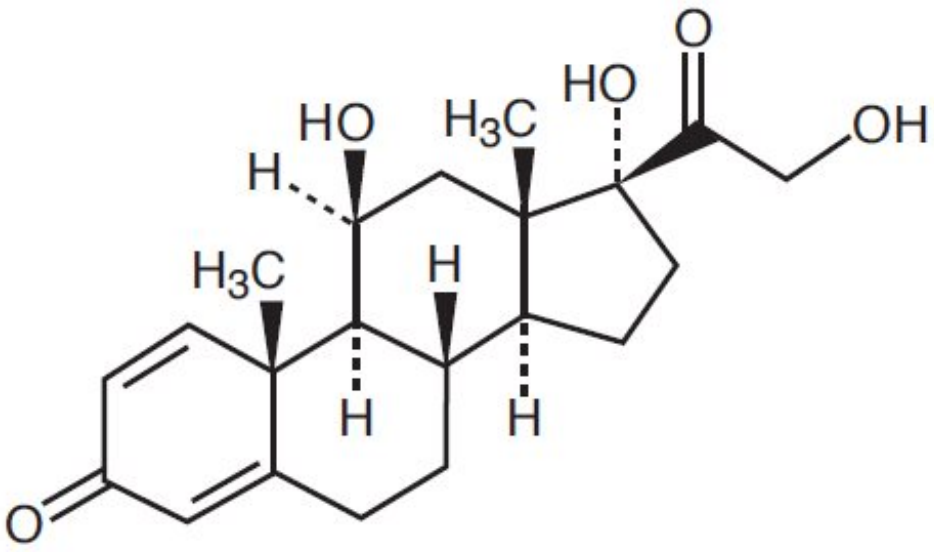
PREDNISOLONE ORAL SOLUTION 15 mg per 5 mL

Rx only

DESCRIPTION

Prednisolone Oral Solution 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, soluble in methanol and in dioxane; sparingly soluble in acetone and in alcohol, slightly soluble in chloroform.

The chemical name for Prednisolone is Pregna-1,4 -diene -3, 20 - dione, 11, 17, 21-trihydroxy-,(11β). Its molecular weight is 360.45. The molecular formula is $C_{21}H_{28}O_5$ and the structural formula is:



Prednisolone Oral Solution contains 15 mg of prednisolone in each 5 mL. Benzoic acid, 0.1% is added as a preservative. It also contains alcohol 5%, citric acid, edetate disodium, glycerin, propylene glycol, purified water, sodium saccharin, sucrose, artificial wild cherry flavor, FD&C blue #1 and red #40.

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 are primarily used for their potent

anti-inflammatory effects in disorders of many organ systems.

Glucocorticoids 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 Oral Solution is indicated in the following conditions:

1. Endocrine Disorders

Primary or secondary adrenocortical insufficiency (hydrocortisone or cortisone is the first choice: synthetic analogs may be used in conjunction with mineralocorticoids where applicable; in infancy mineralocorticoid supplementation is of particular importance).

1. Congenital adrenal hyperplasia
2. Nonsuppurative thyroiditis
3. Hypercalcemia associated with cancer

2. Rheumatic Disorders

As adjunctive therapy for short-term administration (to tide the patient over an acute episode or exacerbation) in:

1. Psoriatic arthritis
2. Rheumatoid arthritis, including juvenile rheumatoid arthritis (selected cases may require low-dose maintenance therapy)
3. Ankylosing spondylitis
4. Acute and subacute bursitis
5. Acute nonspecific tenosynovitis
6. Acute gouty arthritis
7. Post-traumatic osteoarthritis
8. Synovitis of osteoarthritis
9. Epicondylitis

3. Collagen Diseases

During an exacerbation or as maintenance therapy in selected cases of:

1. Systemic lupus erythematosus
2. Acute rheumatic carditis

4. Dermatologic Diseases

1. Pemphigus
2. Bullous dermatitis herpetiformis
3. Severe erythema multiforme (Stevens-Johnson syndrome)
4. Exfoliative dermatitis
5. Mycosis fungoides
6. Severe psoriasis
7. Severe seborrheic dermatitis

5. Allergic States

Control of severe or incapacitating allergic conditions intractable to adequate trials of conventional treatment:

1. Seasonal or perennial allergic rhinitis
2. Bronchial asthma
3. Contact dermatitis
4. Atopic dermatitis
5. Serum sickness
6. Drug hypersensitivity reactions

6. Ophthalmic Diseases

Severe acute and chronic allergic and inflammatory processes involving the eye and its adnexa such as:

1. Allergic corneal marginal ulcers
2. Herpes zoster ophthalmicus
3. Anterior segment inflammation
4. Diffuse posterior uveitis and choroiditis
5. Sympathetic ophthalmia
6. Allergic conjunctivitis
7. Keratitis
8. Chorioretinitis
9. Optic neuritis
10. Iritis and iridocyclitis

7. Respiratory Diseases

Symptomatic sarcoidosis Loeffler’s syndrome not manageable by other means

1. Berylliosis
2. Fulminating or disseminated pulmonary tuberculosis when used concurrently with appropriate chemotherapy
3. Aspiration pneumonitis

8. Hematologic Disorders

Idiopathic thrombocytopenic purpura in adults

Secondary thrombocytopenia in adults

Acquired (autoimmune) hemolytic anemia

Erythroblastopenia (RBC anemia)

Congenital (erythroid) hypoplastic anemia

9. Neoplastic Diseases

For palliative management of:

1. Acute leukemia of childhood
2. Leukemias and lymphomas in adults

10. Edematous States

To induce a diuresis or remission of proteinuria in the nephrotic syndrome, without uremia, of the idiopathic type or that due to lupus erythematosus.

11. Gastrointestinal Diseases

To tide the patient over a critical period of the disease in:
1. Ulcerative colitis
2. Regional enteritis

12. Miscellaneous

Tuberculous meningitis with subarachnoid block or impending block used concurrently with appropriate antituberculous chemotherapy. Trichinosis with neurologic or myocardial involvement.

In addition to the above indications **Prednisolone Oral Solution** is indicated for systemic dermatomyositis (polymyositis).

CONTRAINDICATIONS

Systemic fungal infections.

WARNINGS

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

Corticosteroids may mask some signs of infection, and new infections may appear during their use. There may be decreased resistance and inability to localize infection when corticosteroids are used.

Prolonged use of corticosteroids may produce posterior subcapsular cataracts, glaucoma with possible damage to the optic nerves, and may enhance the establishment of secondary ocular infections 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 the synthetic derivatives except when used in large doses. Dietary salt restriction and potassium supplementation may be necessary. All corticosteroids increase calcium excretion.

While on corticosteroid 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. 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, prophylaxis 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.

The use of **Prednisolone Oral Solution** in active tuberculosis should be restricted to those cases of fulminating or disseminated tuberculosis in which the corticosteroid is used for the management of the disease in conjunction with an appropriate antituberculous regimen.

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.

Use in pregnancy: Since adequate human reproduction studies have not been done with corticosteroids, the use of these drugs in pregnancy, nursing mothers or women of childbearing potential requires that the possible benefits of the drug be weighed against the potential hazards to the mother and embryo or fetus. Infants born of mothers who have received substantial doses of corticosteroids during pregnancy should be carefully observed for signs of hypoadrenalism.

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 reinstituted. Since mineralocorticoid secretion may be impaired, salt and/or a mineralocorticoid should be administered concurrently.

There is an enhanced effect of corticosteroids on 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 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 pyogenic 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

1. Sodium retention
2. Fluid retention
3. Congestive heart failure in susceptible patients
4. Potassium loss
5. Hypokalemic alkalosis
6. Hypertension

Musculoskeletal

1. Muscle weakness
2. Steroid myopathy
3. Loss of muscle mass
4. Osteoporosis
5. Vertebral compression fractures
6. Aseptic necrosis of femoral and humeral heads
7. Pathologic fracture of long bones

Gastrointestinal

1. Peptic ulcer with possible perforation and hemorrhage
2. Pancreatitis
3. Abdominal distention
4. Ulcerative esophagitis

Dermatologic

1. Impaired wound healing
2. Thin fragile skin
3. Petechiae and ecchymoses
4. Facial erythema
5. Increased sweating
6. May suppress reactions to skin tests

Neurological

1. Convulsions
2. Increased intracranial pressure with papilledema (pseudo-tumor cerebri) usually after treatment
3. Vertigo
4. Headache

Endocrine

1. Menstrual irregularities
2. Development of Cushingoid state

3. Suppression of growth in children
4. Secondary adrenocortical and pituitary unresponsiveness, particularly in times of stress, as in trauma, surgery or illness
5. Decreased carbohydrate tolerance
6. Manifestations of latent diabetes mellitus
7. Increased requirements for insulin or oral hypoglycemic agents in diabetics

Ophthalmic
1. Posterior subcapsular cataracts
2. Increased intraocular pressure
3. Glaucoma
4. Exophthalmos

Metabolic
1. Negative nitrogen balance due to protein catabolism

To report SUSPECTED ADVERSE REACTIONS, contact Hi-Tech Pharmacal Co., Inc. at 1-800-262-9010 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

DOSAGE AND ADMINISTRATION

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

Pharmacist: Dispense 15 mg/5 mL Prednisolone Oral Solution with suitable calibrated measuring device to assure proper measuring of dose.

DOSE/VOLUME CHART

15 mg prednisolone	=	1 teaspoon
10 mg prednisolone	=	2/3 teaspoon
7.5 mg prednisolone	=	1/2 teaspoon
5 mg prednisolone	=	1/3 teaspoon

Dispense in tight, light-resistant and child-resistant container as defined in USP/NF.

Store at 20° to 25°C (68° to 77°F) [See USP Controlled Room Temperature]. DO NOT REFRIGERATE.

HI-TECH PHARMACAL CO., INC.

Amityville, NY 11701

Rev.042:05 01/17

PACKAGE/LABEL PRINCIPAL DISPLAY PANEL

AKORN

50383-042-48

PrednisoLONE Oral Solution, USP

15 mg per 5 mL

Rx only

480 mL

USUAL DOSAGE: See accompanying circular.

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

Store at 20° to 25°C (68° to 77°F) [See USP Controlled Room Temperature]. DO NOT REFRIGERATE.

PHARMACIST: Dispense with a suitable Calibrated Measuring Device.

For your convenience, calibrated teaspoons are enclosed.

DESCRIPTION: PREDISOLONE ORAL SOLUTION, USP contains 15 mg of PREDNISOLONE in each 5 mL (teaspoonful and alcohol 5% (v/v). Benzoic acid 0.1% added as a preservative.

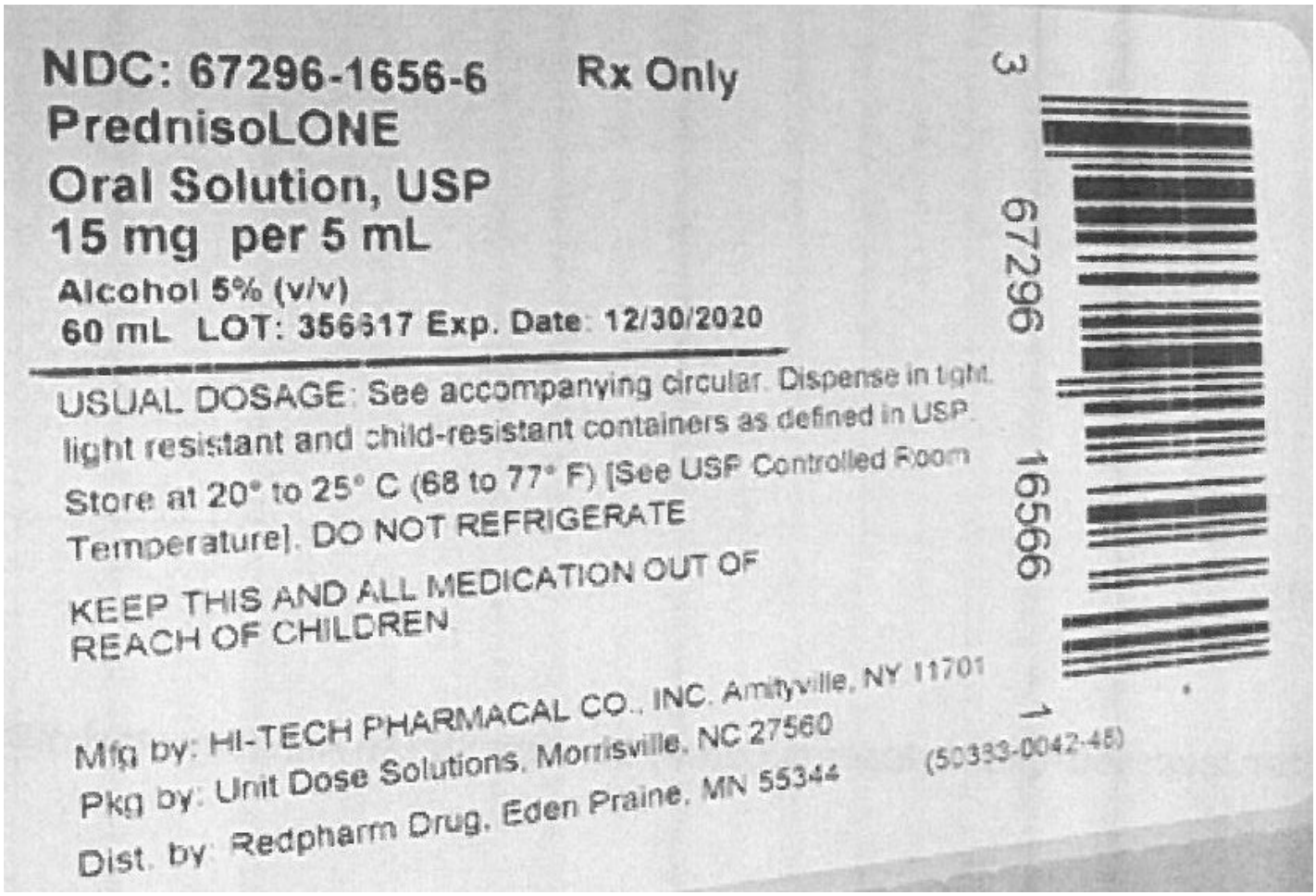
Alcohol 5% (v/v)

HI-TECH PHARMACAL CO., INC.

Amityville, NY 11701

MADE IN U.S.A.

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL



PREDNISOLONE

prednisolone solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:67296-1656(NDC:50383-042)
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
PREDNISOLONE (UNII: 9PHQ9Y1OLM) (PREDNISOLONE - UNII:9PHQ9Y1OLM)	PREDNISOLONE	15 mg in 5 mL

Inactive Ingredients	
Ingredient Name	**Strength**
ALCOHOL (UNII: 3K9958V90M)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	

BENZOIC ACID (UNII: 8SKN0B0MIM)	
CHERRY (UNII: BUC5I9595W)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SUCROSE (UNII: C151H8M554)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67296-1656-6	60 mL in 1 BOTTLE; Type 0: Not a Combination Product	02/27/2003	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA040401	02/27/2003	

Labeler - RedPharm Drug, Inc. (828374897)

Establishment

Name	Address	ID/FEI	Business Operations
EPM Packaging, Inc.		079124340	repack(67296-1656)

Revised: 1/2022 RedPharm Drug, Inc.