

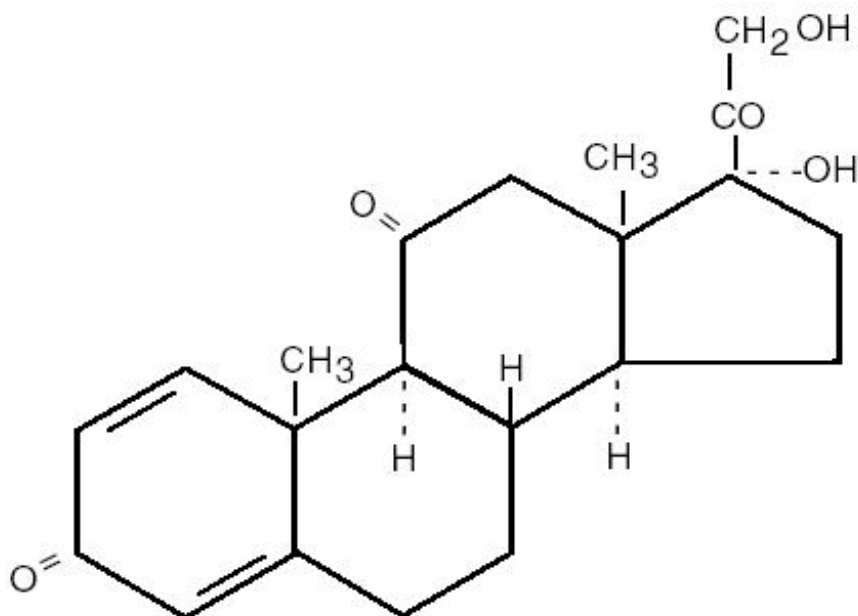
**PREDNISONE - prednisone tablet**  
**Keltman Pharmaceuticals Inc.**

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**PREDNISONE TABLETS**

**Rx Only**

**DESCRIPTION**

Prednisone is a glucocorticoid. Glucocorticoids are adrenocortical steroids, both naturally occurring and synthetic, that are readily absorbed from the gastrointestinal tract. The formula for prednisone is  $C_{21}H_{26}O_5$ . Chemically, it is 17,21-dihydroxypregna-1, 4-diene-3,11, 20-trione and has the following structural formula:



Prednisone is a white to practically white, odorless, crystalline powder and has a molecular weight of 358.43. It melts at about 230°C with some decomposition. Prednisone is very slightly soluble in water, slightly soluble in alcohol, chloroform, dioxane, and methanol.

Each tablet, for oral administration, contains 5 mg, 10 mg, and 20 mg prednisone.

Inactive ingredients are as follows:

**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.

**20 mg:** anhydrous lactose, D&C Yellow No. 10 Aluminum Lake, FD&C Yellow No. 6 Aluminum Lake, magnesium stearate, microcrystalline cellulose, and sodium starch glycolate.

**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 antiinflammatory 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:* 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), congenital adrenal hyperplasia, nonsuppurative thyroiditis, hypercalcemia associated with cancer.

*Rheumatic disorders:* as adjunctive therapy for short-term administration (to tide the patient over an acute episode or exacerbation) in; psoriatic arthritis; rheumatoid arthritis, including juvenile rheumatoid arthritis (selected cases may require low-dose maintenance therapy); ankylosing spondylitis; acute and subacute bursitis; acute nonspecific tenosynovitis; acute gouty arthritis; post-traumatic osteoarthritis; synovitis of osteoarthritis; epicondylitis.

*Collagen diseases:* during an exacerbation or as maintenance therapy in selected cases of: systemic lupus erythematosus, acute rheumatic carditis.

*Dermatologic diseases:* pemphigus, bullous dermatitis herpetiformis, severe erythema multiforme (Stevens-Johnson syndrome), exfoliative dermatitis, mycosis fungoides, severe seborrheic dermatitis.

*Allergic states:* control of severe or incapacitating allergic conditions intractable to adequate trials of conventional treatment: seasonal or perennial allergic rhinitis, serum sickness, bronchial asthma, contact dermatitis, atopic dermatitis, drug hypersensitivity reactions.

*Ophthalmic diseases:* severe acute and chronic allergic and inflammatory processes involving the eye and its adnexa, such as: allergic conjunctivitis, keratitis, allergic corneal marginal ulcers, herpes zoster ophthalmicus, iritis and iridocyclitis, chorioretinitis, anterior segment inflammation, diffuse posterior uveitis and choroiditis, optic neuritis, sympathetic ophthalmia.

*Respiratory diseases:* symptomatic sarcoidosis, Loeffler's syndrome not manageable by other means, berylliosis, fulminating or disseminated pulmonary tuberculosis when used concurrently with appropriate antituberculous chemotherapy, aspiration pneumonitis.

*Hematologic disorders:* Idiopathic thrombocytopenic purpura in adults, secondary thrombocytopenia in adults, acquired (autoimmune) hemolytic anemia, erythroblastopenia (RBC anemia), congenital (erythroid) hypoplastic anemia.

*Neoplastic diseases:* for palliative management of: leukemias and lymphomas in adults, acute leukemia of childhood.

*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.

*Gastrointestinal diseases:* to tide the patient over a critical period of the disease in: ulcerative colitis, regional enteritis.

*Miscellaneous:* tuberculous meningitis with subarachnoid block or impending block when used concurrently with appropriate antituberculous chemotherapy, trichinosis with neurologic or myocardial involvement.

In addition to the above indications, prednisone tablets are indicated for systemic dermatomyositis (polymyositis).

## CONTRAINDICATIONS

Prednisone tablets are contraindicated in 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 doses, because of possible hazards of neurological complications and a lack of antibody response.*

Persons who are on drugs that 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 intravenous 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 prednisone tablets 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.

*Usage 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 reinstated. 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 infection; diverticulitis; fresh intestinal anastomosis; 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:** 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 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, hypokalemic alkalosis, hypertension.

*Musculoskeletal:* muscle weakness, steroid myopathy, loss of muscle mass, osteoporosis, vertebral compression fractures, aseptic necrosis of femoral and humeral heads, pathological 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 diabetics.

*Ophthalmic:* posterior subcapsular cataracts, increased intraocular pressure, glaucoma, exophthalmos.

*Metabolic:* negative nitrogen balance due to protein catabolism.

## **DOSAGE AND ADMINISTRATION**

Dosage of prednisone tablets 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 prednisone 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, prednisone 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 adjustment 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 prednisone 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

Prednisone Tablets USP, 5 mg: White, round tablets, scored on one side and "West-ward 475" debossed on the other side. Each tablet contains 5 mg of prednisone for oral administration.

Prednisone Tablets USP, 10 mg: White, round tablets, scored on one side and "West-ward 473" debossed on the other side. Each tablet contains 10 mg of prednisone for oral administration.

Prednisone Tablets USP, 20 mg: Peach colored, round tablets, scored on one side and "Westward 477" debossed on the other side. Each tablet contains 20 mg of prednisone for oral administration.

They are supplied by **Keltman Pharmaceuticals Inc.** as follows:

NDC	Strength	Quantity/Form	Color	Source Prod. Code
68387-240-10	20 mg	10 Tablets in a Plastic Bottle	ORANGE	0143-1477
68387-240-25	20 mg	25 Tablets in a Plastic Bottle	ORANGE	0143-1477
68387-241-15	10 mg	15 Tablets in a Plastic Bottle	WHITE	0143-1473

Store at 20°-25°C (68°-77°F) [See USP Controlled Room Temperature]. Protect from light and moisture.

Dispense in a tight, light-resistant container as defined in the USP using a child-resistant closure.

Manufactured for:

**West-ward Pharmaceutical Corp.**

Eatontown, NJ 07724

This Product was Repackaged By Sandhills Packaging for:

**Keltman Pharmaceuticals Inc.**

1 Lakeland Square, Suite A

Flowood, MS 39232

United States

### Label Image for 10mg

**Keltman Pharmaceuticals, Inc.**  
NDC: 68387-241-15  
**Prednisone 10mg**  
15 Tablets  
Each tablet contains 10mg prednisone  
Rx Only  
Lot: 66809A 1 Exp: 5/2013 Rx #: 34941  
Store at controlled room temperature 20-25 C (68-77 F).  
Keep out of reach of children. Dosage: See package insert  
Caution: Federal law prohibits transfer of this drug to any person other than the patient for whom prescribed.  
Manufactured by: West-ward Pharmaceutical Corp., Eatontown, NJ 07724  
Distributed by: Keltman Pharmaceuticals, Inc. Flowood, MS 39232  
Call your doctor for medical advice about side effects.  
You may report side effects to FDA at 1-800-FDA-1088.

68387-0241-15++66809A1  
Take \_\_\_ tablet(s) \_\_\_ time(s) daily or  
every \_\_\_ hours for \_\_\_ days

NDC: 68387-241-15 Rx #: 34941  
Prednisone 10mg (prednisone)  
Lot: 66809A 1 Exp: 5/2013  
Chart

NDC: 68387-241-15 Rx #: 34941  
Prednisone 10mg (prednisone)  
Lot: 66809A 1 Exp: 5/2013  
Patient

NDC: 68387-241-15 Rx #: 34941  
Prednisone 10mg (prednisone)  
Lot: 66809A 1 Exp: 5/2013  
Bill

NDC: 68387-241-15 Rx #: 34941  
Prednisone 10mg (prednisone)  
Lot: 66809A 1 Exp: 5/2013  
Log

### Label Image for 20mg

# Keltman Pharmaceuticals, Inc.

68387-0240-10++64249A1



Take \_\_\_ tablet(s) \_\_\_ time(s)  
daily or every \_\_\_ hours for \_\_\_  
days.

**NDC: 68387 – 240 – 10**

**Prednisone 20mg**

**10 Tablets**

Each tablet contains 20mg prednisone

Lot: 64249A 1 Exp: 2/2012

**Rx Only**

Rx #: 168280

Store at controlled room temperature 20-25 C (68-77 F).

Keep out of reach children. Dosage: See package insert  
Caution: Federal law prohibits transfer of this drug to any  
person other than the patient for whom prescribed.

Manufactured by: West-ward Pharmaceutical Corp., Eatontown, NJ 07724  
Distributed by: Keltman Pharmaceuticals, Inc. Flowood, MS 39232

NDC: 68387-240-10 Rx #: 168280  
Prednisone 20mg  
(prednisone)  
Lot: 64249A 1 Exp: 2/2012

Chart

NDC: 68387-240-10 Rx #: 168280  
Prednisone 20mg  
(prednisone)  
Lot: 64249A 1 Exp: 2/2012

Patient

NDC: 68387-240-10 Rx #: 168280  
Prednisone 20mg  
(prednisone)  
Lot: 64249A 1 Exp: 2/2012

Bill

NDC: 68387-240-10 Rx #: 168280  
Prednisone 20mg  
(prednisone)  
Lot: 64249A 1 Exp: 2/2012

Log

## PREDNISONE

prednisone tablet

### Product Information

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:68387-240(NDC:0143-1477)
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PREDNISONE (UNII: VB0R961HZT) (PREDNISONE - UNII:VB0R961HZT)	PREDNISONE	20 mg

### Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	

### Product Characteristics

<b>Color</b>	ORANGE (ORANGE)	<b>Score</b>	2 pieces
<b>Shape</b>	ROUND (ROUND)	<b>Size</b>	9mm
<b>Flavor</b>		<b>Imprint Code</b>	Westward;477
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68387-240-10	10 in 1 BOTTLE, PLASTIC		
2	NDC:68387-240-25	25 in 1 BOTTLE, PLASTIC		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA083677	04/23/2007	

## PREDNISONONE

prednisone tablet

### Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:68387-241(NDC:0143-1473)
Route of Administration	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PREDNISONONE (UNII: VB0R961HZT) (PREDNISONONE - UNII:VB0R961HZT)	PREDNISONONE	10 mg

### Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
TALC (UNII: 7SEV7J4R1U)	

### Product Characteristics

Color	WHITE (WHITE)	Score	2 pieces
Shape	ROUND (ROUND)	Size	9mm
Flavor		Imprint Code	Westward;473
Contains			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68387-241-15	15 in 1 BOTTLE, PLASTIC		



## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA083677	07/07/2008	

**Labeler** - Keltman Pharmaceuticals Inc. (362861077)

## Establishment

Name	Address	ID/FEI	Business Operations
Sandhills Packaging		825138717	repack

Revised: 6/2010

Keltman Pharmaceuticals Inc.