

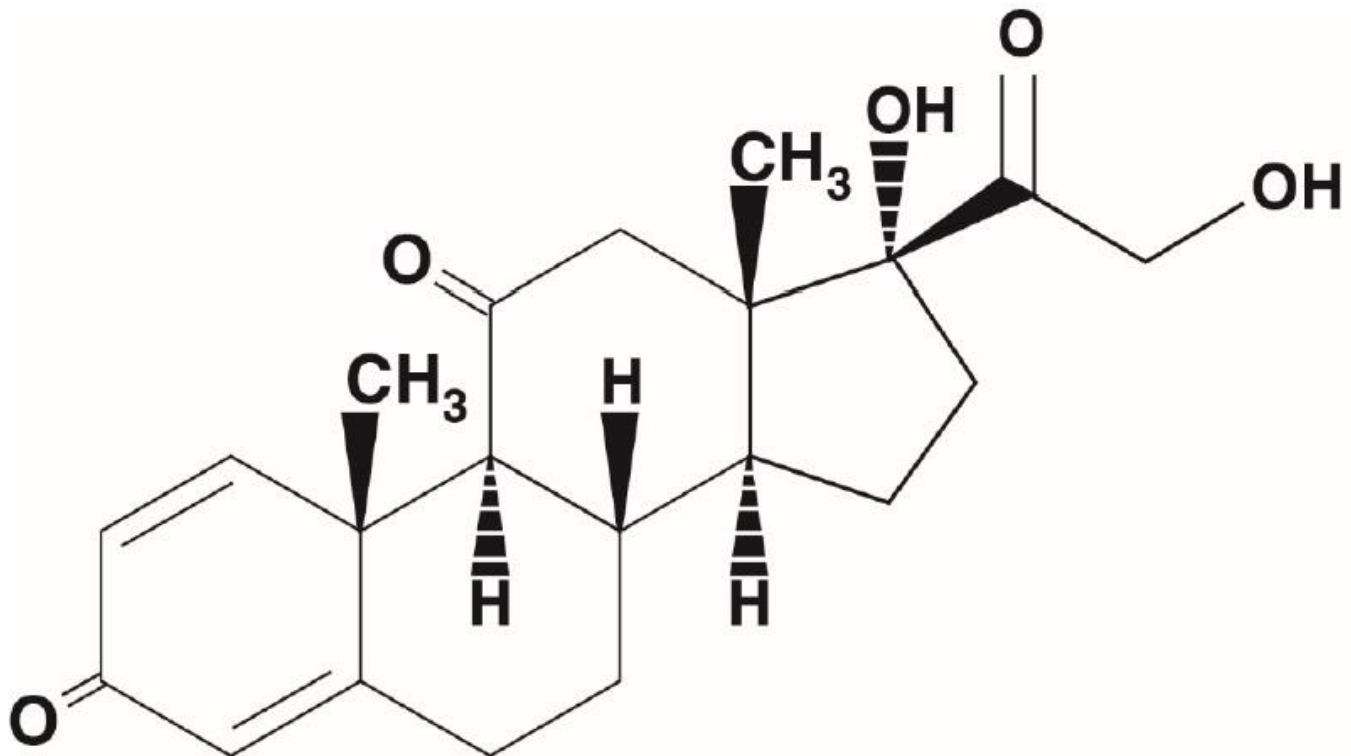
PREDNISONE - prednisone tablet
ANI Pharmaceuticals, Inc.

PredniSONE Tablets, USP 2.5mg, 5mg, 10mg, 20mg & 50mg
Rx only

DESCRIPTION

Prednisone Tablets, USP are available for oral administration containing 2.5 mg, 5 mg, 10 mg, 20 mg and 50 mg of prednisone, USP. Each tablet contains the following inactive ingredients: lactose monohydrate, magnesium stearate, microcrystalline cellulose, pregelatinized starch, sodium lauryl sulfate and sodium starch glycolate.

Prednisone Tablets, USP contain prednisone which is a glucocorticoid. Glucocorticoids are adrenocortical steroids, both naturally occurring and synthetic, which are readily absorbed from the gastrointestinal tract. The chemical name for prednisone is pregna-1,4-diene-3,11,20-trione, 17,21-dihydroxy-. The structural formula is represented below:



Molecular Formula: C₂₁H₂₆O₅

Molecular Weight: 358.44

Prednisone is a white or almost white crystalline powder. It is slightly soluble in acetone, ethanol, ethylacetate and methanol.

Meets USP Dissolution Test 2.

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 are primarily used for their potent anti-inflammatory effects in disorders of many organ systems.

Glucocorticoids cause profound and varied metabolic effects. In addition, they modify the body's immune responses to diverse stimuli.

INDICATIONS & USAGE

Prednisone Tablets, USP 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, Hypercalcemia associated with cancer, nonsuppurative thyroiditis

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, systemic dermatomyositis (polymyositis), acute rheumatic carditis.

Dermatologic Diseases

Pemphigus, Bullous dermatitis herpetiformis, severe erythema multiforme (Stevens-Johnson syndrome), exfoliative dermatitis, mycosis fungoides, severe psoriasis, severe seborrheic dermatitis.

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, atopic dermatitis, serum sickness, drug hypersensitivity reactions.

Ophthalmic Diseases

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

Respiratory Diseases

Symptomatic sarcoidosis, Löeffler'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

Nervous System

Acute exacerbations of multiple sclerosis

Miscellaneous

Tuberculous meningitis with subarachnoid block or impending block when used concurrently with appropriate antituberculous chemotherapy, trichinosis with neurologic or myocardial involvement

CONTRAINDICATIONS

Prednisone Tablets are contraindicated in systemic fungal infections and known hypersensitivity to components.

WARNINGS**General**

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

Immunosuppression and Increased Risk of Infection

Corticosteroids, including prednisone, suppress the immune system and increase the risk of infection with any pathogen, including viral, bacterial, fungal, protozoan, or helminthic pathogens. Corticosteroids can:

- Reduce resistance to new infections
- Exacerbate existing infections
- Increase the risk of disseminated infections
- Increase the risk of reactivation or exacerbation of latent infections
- Mask some signs of infection

Corticosteroid-associated infections can be mild but can be severe and at times fatal. The rate of infectious complications increases with increasing corticosteroid dosages.

Monitor for the development of infection and consider prednisone withdrawal or dosage reduction as needed.

Tuberculosis

If prednisone is used to treat a condition in patients with latent tuberculosis or tuberculin reactivity, reactivation of tuberculosis may occur. Closely monitor such patients for reactivation. During prolonged prednisone therapy, patients with latent tuberculosis or tuberculin reactivity should receive chemoprophylaxis.

Varicella Zoster and Measles Viral Infections

Varicella and measles can have a serious or even fatal course in non-immune patients taking corticosteroids, including prednisone. In corticosteroid-treated patients who have not had these diseases or are non-immune, particular care should be taken to avoid exposure to varicella and measles:

- If a prednisone-treated patient is exposed to varicella, prophylaxis with varicella zoster immune globulin may be indicated. If varicella develops, treatment with antiviral agents may be considered.
- If a prednisone-treated patient is exposed to measles, prophylaxis with immunoglobulin may be indicated.

Hepatitis B Virus Reactivation

Hepatitis B virus reactivation can occur in patients who are hepatitis B carriers treated with immunosuppressive dosages of corticosteroids, including prednisone. Reactivation can also occur infrequently in corticosteroid-treated patients who appear to have resolved hepatitis B infection.

Screen patients for hepatitis B infection before initiating immunosuppressive (e.g., prolonged) treatment with prednisone. For patients who show evidence of hepatitis B infection, recommend consultation with physicians with expertise in managing hepatitis B regarding monitoring and consideration for hepatitis B antiviral therapy.

Fungal Infections

Corticosteroids, including prednisone, may exacerbate systemic fungal infections; therefore, avoid prednisone use in the presence of such infections unless prednisone is needed to control drug reactions. For patients on chronic prednisone therapy who develop systemic fungal infections, prednisone withdrawal or dosage reduction is recommended.

Amebiasis

Corticosteroids, including prednisone, may activate latent amebiasis. Therefore, it is recommended that latent amebiasis or active amebiasis be ruled out before initiating prednisone in patients who have spent time in the tropics or patients with unexplained diarrhea.

Strongyloides Infestation

Corticosteroids, including prednisone, 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.

Cerebral Malaria

Avoid corticosteroids, including prednisone, in patients with cerebral malaria.

Kaposi's Sarcoma

Kaposi's sarcoma has been reported to occur in patients receiving corticosteroid therapy, most often for chronic conditions. Discontinuation of corticosteroids may result in clinical improvement of Kaposi's sarcoma.

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.

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.

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.

PRECAUTIONS

GENERAL PRECAUTIONS

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 infection: 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.

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 cyclosporine. Since concurrent use 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.

INFORMATION FOR PATIENTS

Patients who are on immunosuppressant doses of corticosteroids should be warned to avoid exposure to chickenpox or measles and, if exposed, to obtain medical advice.

ADVERSE REACTIONS

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
- 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

Metabolic

- Negative nitrogen balance due to protein catabolism

Neurological

- Increased intracranial pressure with papilledema (pseudo-tumor cerebri) usually after treatment
- Convulsions
- Vertigo
- Headache

Endocrine

- Menstrual irregularities
- Development of Cushingoid state
- Secondary adrenocortical and pituitary unresponsiveness, particularly in times of stress, as in trauma, surgery or illness
- Suppression of growth in children
- 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

Additional Reactions

- Urticaria and other allergic, anaphylactic or hypersensitivity reactions

DOSAGE & ADMINISTRATION

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 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 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.

Multiple Sclerosis

In the treatment of acute exacerbations of multiple sclerosis daily doses of 200 mg of prednisolone for a week followed by 80 mg every other day for 1 month have been shown to be effective. (Dosage range is the same for prednisone and prednisolone.)

Alternate Day Therapy

Alternate day therapy is a corticosteroid dosing regimen in which twice the usual daily dose of corticoid is administered every other morning. The purpose of this mode of therapy is to provide the patient requiring long-term pharmacologic dose treatment with the beneficial effects of corticoids while minimizing certain undesirable effects, including pituitary-adrenal suppression, the cushingoid state, corticoid withdrawal symptoms, and growth suppression in children.

The rationale for this treatment schedule is based on two major premises: (a) the anti-inflammatory or therapeutic effect of corticoids persists longer than their physical presence and metabolic effects and (b) administration of the corticosteroid every other morning allows for re-establishment of more nearly normal hypothalamic-pituitary-adrenal (HPA) activity on the off-steroid day.

A brief review of the HPA physiology may be helpful in understanding 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 ACTH secretion. Normally the HPA system is characterized by diurnal (circadian) rhythm. Serum levels of ACTH rise from a low point about 10 pm to a peak level about 6 am. Increasing levels of ACTH stimulate adrenocortical activity resulting in a rise in plasma cortisol with maximal levels occurring between 2 am and 8 am. This rise in cortisol dampens ACTH production and in turn adrenocortical activity. There is a gradual fall in plasma corticoids during the day with lowest levels occurring about midnight.

The diurnal rhythm of the HPA axis is lost in Cushing's disease, a syndrome of adrenocortical hyperfunction characterized by obesity with centripetal fat distribution, thinning of the skin with easy bruisability, muscle wasting with weakness, hypertension, latent diabetes, osteoporosis, electrolyte imbalance, etc. The same clinical findings of hyperadrenocorticism may be noted during long-term pharmacologic dose corticoid therapy administered in conventional daily divided doses. It would appear, then, that a

disturbance in the diurnal cycle with maintenance of elevated corticoid values during the night may play a significant role in the development of undesirable corticoid effects. Escape from these constantly elevated plasma levels for even short periods of time may be instrumental in protecting against undesirable pharmacologic effects.

During conventional pharmacologic dose corticosteroid therapy, ACTH production is inhibited with subsequent suppression of cortisol production by the adrenal cortex. Recovery time for normal HPA activity is variable depending upon the dose and duration of treatment. During this time the patient is vulnerable to any stressful situation. Although it has been shown that there is considerably less adrenal suppression following a single morning dose of prednisolone (10 mg) as opposed to a quarter of that dose administered every 6 hours, there is evidence that some suppressive effect on adrenal activity may be carried over into the following day when pharmacologic doses are used. Further, it has been shown that a single dose of certain corticosteroids will produce adrenocortical suppression for two or more days. Other corticoids, including methylprednisolone, hydrocortisone, prednisone, and prednisolone, are considered to be short acting (producing adrenocortical suppression for 1¼ to 1½ days following a single dose) and thus are recommended for alternate day therapy.

The following should be kept in mind when considering alternate day therapy:

1. Basic principles and indications for corticosteroid therapy should apply. The benefits of alternate day therapy should not encourage the indiscriminate use of steroids.
2. Alternate day therapy is a therapeutic technique primarily designed for patients in whom long-term pharmacologic corticoid therapy is anticipated.
3. In less severe disease processes in which corticoid therapy is indicated, it may be possible to initiate treatment with alternate day therapy. More severe disease states usually will require daily divided high dose therapy for initial control of the disease process. The initial suppressive dose level should be continued until satisfactory clinical response is obtained, usually four to ten days in the case of many allergic and collagen diseases. It is important to keep the period of initial suppressive dose as brief as possible particularly when subsequent use of alternate day therapy is intended. Once control has been established, two courses are available: (a) change to alternate day therapy and then gradually reduce the amount of corticoid given every other day or (b) following control of the disease process reduce the daily dose of corticoid to the lowest effective level as rapidly as possible and then change over to an alternate day schedule. Theoretically, course (a) may be preferable.
4. Because of the advantages of alternate day therapy, it may be desirable to try patients on this form of therapy who have been on daily corticoids for long periods of time (e.g., patients with rheumatoid arthritis). Since these patients may already have a suppressed HPA axis, establishing them on alternate day therapy may be difficult and not always successful. However, it is recommended that regular attempts be made to change them over. It may be helpful to triple or even quadruple the daily maintenance dose and administer this every other day rather than just doubling the daily dose if difficulty is encountered. Once the patient is again controlled, an attempt should be made to reduce this dose to a minimum.
5. As indicated above, certain corticosteroids, because of their prolonged suppressive effect on adrenal activity, are not recommended for alternate day therapy (e.g., dexamethasone and betamethasone).
6. The maximal activity of the adrenal cortex is between 2 am and 8 am, and it is minimal between 4 pm and midnight. Exogenous corticosteroids suppress adrenocortical activity the least, when given at the time of maximal activity (am).

7. In using alternate day therapy it is important, as in all therapeutic situations to individualize and tailor the therapy to each patient. Complete control of symptoms will not be possible in all patients. An explanation of the benefits of alternate day therapy will help the patient to understand and tolerate the possible flare-up in symptoms which may occur in the latter part of the off-steroid day. Other symptomatic therapy may be added or increased at this time if needed.
8. In the event of an acute flare-up of the disease process, it may be necessary to return to a full suppressive daily divided corticoid dose for control. Once control is again established alternate day therapy may be re-instituted.
9. Although many of the undesirable features of corticosteroid therapy can be minimized by alternate day therapy, as in any therapeutic situation, the physician must carefully weigh the benefit-risk ratio for each patient in whom corticoid therapy is being considered.

HOW SUPPLIED

Prednisone Tablets, USP are available in the following strengths and package sizes:

Prednisone Tablets, USP 2.5 mg for oral administration are supplied as follows:

White to off white, round tablet, debossed with “057” on one side and bisect on the other side.

NDC 70954-**057**-10 Bottles of 100 Tablets with child resistant caps

Prednisone Tablets, USP 5 mg for oral administration are supplied as follows:

White to off white, round tablet, debossed with “058” on one side and bisect on the other side.

NDC 70954-**058**-10 Bottles of 100 Tablets with child resistant caps

NDC 70954-**058**-20 Bottles of 1000 Tablets with child resistant caps

NDC 70954-**058**-30 Blister Packs (Unit-of-Use 21 Tablets)

NDC 70954-**058**-40 Blister Packs (Unit-of-Use 48 Tablets)

Prednisone tablets, USP 10 mg for oral administration are supplied as follows:

White to off white, round tablet, debossed with “059” on one side and bisect on the other side.

NDC 70954-**059**-10 Bottles of 100 Tablets with child resistant caps

NDC 70954-**059**-20 Bottles of 1000 Tablets with child resistant caps

NDC 70954-**059**-30 Blister Packs (Unit-of-Use 21 Tablets)

NDC 70954-**059**-40 Blister Packs (Unit-of-Use 48 Tablets)

Prednisone tablets, USP 20 mg for oral administration are supplied as follows:

White to off white, round tablet, debossed with “060” on one side and bisect on the other side.

NDC 70954-**060**-10 Bottles of 100 Tablets with child resistant caps

NDC 70954-**060**-20 Bottles of 500 Tablets with child resistant caps

NDC 70954-**060**-30 Bottles of 1000 Tablets with child resistant caps

Prednisone tablets, USP 50 mg for oral administration are supplied as follows:

White to off white, round tablet, debossed with “061” on one side and bisect on the other side.

NDC 70954-**061**-10 Bottles of 100 Tablets with child resistant caps

Store at 20°C to 25°C (68°F to 77°F). [See USP Controlled Room Temperature.]

Protect from moisture.

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

Manufactured by:

Novitium Pharma LLC

70 Lake Drive, East Windsor

New Jersey 08520

Issued: 02/2024

LB4212-04

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL



PredniSONE Tablets, USP 2.5 mg

PredniSONE Tablets, USP 2.5 mg 100 Counts



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| <p>NDC 70954-057-10 100 Tablets</p> <h1>PredniSONE</h1> <h2>Tablets, USP</h2> <div style="background-color: green; color: white; padding: 5px; border-radius: 10px; display: inline-block;"> 2.5 mg </div> <p>Each tablet contains 2.5 mg of prednisone, USP.</p> <div>  <div style="margin-left: 20px;"> Rx only </div> </div> | <p>Usual Dosage: See accompanying package insert for complete prescribing information.</p> <p>Store at 20°C to 25°C (68°F to 77°F). [See USP Controlled Room Temperature].</p> <p>Protect from moisture.</p> <p>Dispense in a tight, light-resistant container as defined in the USP. Keep container tightly closed.</p> <p>This package is child-resistant.</p> <p>Keep this and all medications out of the reach of children.</p> <p>Manufactured by: Novitium Pharma LLC 70 Lake Drive, East Windsor New Jersey 08520 Revised: 03/19</p> <p style="text-align: right;">LB4086-01</p> |  <p style="writing-mode: vertical-rl; transform: rotate(180deg);">N 3 70954-057-10 9</p> | <p style="writing-mode: vertical-rl; transform: rotate(180deg); color: orange; font-weight: bold; font-size: 24px;">NO VARNISH</p> |
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PredniSONE Tablets, USP 5 mg

PredniSONE Tablets, USP 5 mg 100 counts

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|---|---|--|--|
| <p>NDC 70954-058-10 100 Tablets</p> <h1>PredniSONE</h1> <h2>Tablets, USP</h2> <div style="background-color: blue; color: white; padding: 5px; border-radius: 10px; display: inline-block;"> 5 mg </div> <p>Each tablet contains 5 mg of prednisone, USP.</p> <div>  <div style="margin-left: 20px;"> Rx only </div> </div> | <p>Usual Dosage: See accompanying package insert for complete prescribing information.</p> <p>Store at 20°C to 25°C (68°F to 77°F). [See USP Controlled Room Temperature].</p> <p>Protect from moisture.</p> <p>Dispense in a tight, light-resistant container as defined in the USP. Keep container tightly closed.</p> <p>This package is child-resistant.</p> <p>Keep this and all medications out of the reach of children.</p> <p>Manufactured by: Novitium Pharma LLC 70 Lake Drive, East Windsor New Jersey 08520 Revised: 03/19</p> <p style="text-align: right;">LB4088-01</p> |  <p style="writing-mode: vertical-rl; transform: rotate(180deg);">N 3 70954-058-10 6</p> | <p style="writing-mode: vertical-rl; transform: rotate(180deg); color: orange; font-weight: bold; font-size: 24px;">NO VARNISH</p> |
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PredniSONE Tablets, USP 5 mg 1000 counts

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|---|---|---|--|
| <p>NDC 70954-058-20 1,000 Tablets</p> <h1>PredniSONE</h1> <h2>Tablets, USP</h2> <div style="background-color: blue; color: white; padding: 5px; border-radius: 10px; display: inline-block;"> 5 mg </div> <p>Each tablet contains 5 mg of prednisone, USP.</p> <div>  <div style="margin-left: 20px;"> Rx only </div> </div> | <p>Usual Dosage: See accompanying package insert for complete prescribing information.</p> <p>Store at 20°C to 25°C (68°F to 77°F). [See USP Controlled Room Temperature].</p> <p>Protect from moisture.</p> <p>Dispense in a tight, light-resistant container as defined in the USP. Keep container tightly closed.</p> <p>This package is child-resistant.</p> <p>Keep this and all medications out of the reach of children.</p> <p>Manufactured by: Novitium Pharma LLC 70 Lake Drive, East Windsor New Jersey 08520 Revised: 03/19</p> <p style="text-align: right;">LB4089-01</p> |  <p style="writing-mode: vertical-rl; transform: rotate(180deg);">N 3 70954-058-20 5</p> | <p style="writing-mode: vertical-rl; transform: rotate(180deg); color: orange; font-weight: bold; font-size: 24px;">NO VARNISH</p> |
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PredniSONE Tablets, USP 5 mg Blister Packs (Unit-of-Use 21 Tablets)

TAB

PredniSONE Tablets, USP 5 mg
Gently peel back outer layer at TAB before pushing tablet out of foil.
Dosage Directions (*see Additional Instructions below)

Unit of Use
21 Tablets

Do NOT discard daily Dosage Directions

**1ST
DAY**

Take 2 tablets before
breakfast.

Take 1
tablet after
lunch.

Take 1
tablet after
supper.

Take 2 tablets at
bedtime.

TAB

**2ND
DAY**

Take 1
tablet
before
breakfast.

Take 1
tablet after
lunch.

Take 1
tablet after
supper.

Take 2 tablets at
bedtime.

**PredniSONE
Tablets, USP
5 mg**

LB4572-03
Rev: 12/24

TAB

**3RD
DAY**

Take 1
tablet
before
breakfast.

Take 1
tablet after
lunch.

Take 1
tablet after
supper.

Take 1
tablet at
bedtime.

TAB

**4TH
DAY**

Take 1
tablet
before
breakfast.

Take 1
tablet after
lunch.

Take 1
tablet at
bedtime.

TAB

**5TH
DAY**

Take 1
tablet
before
breakfast.

Take 1
tablet at
bedtime.

TAB

***Additional Instructions:** Unless otherwise directed by your physician, all six (6) tablets in the row labeled 1ST DAY should be taken the day you receive your prescription. If it is received late in the day, take two tablets every hour for the first day only, then follow directions as printed.

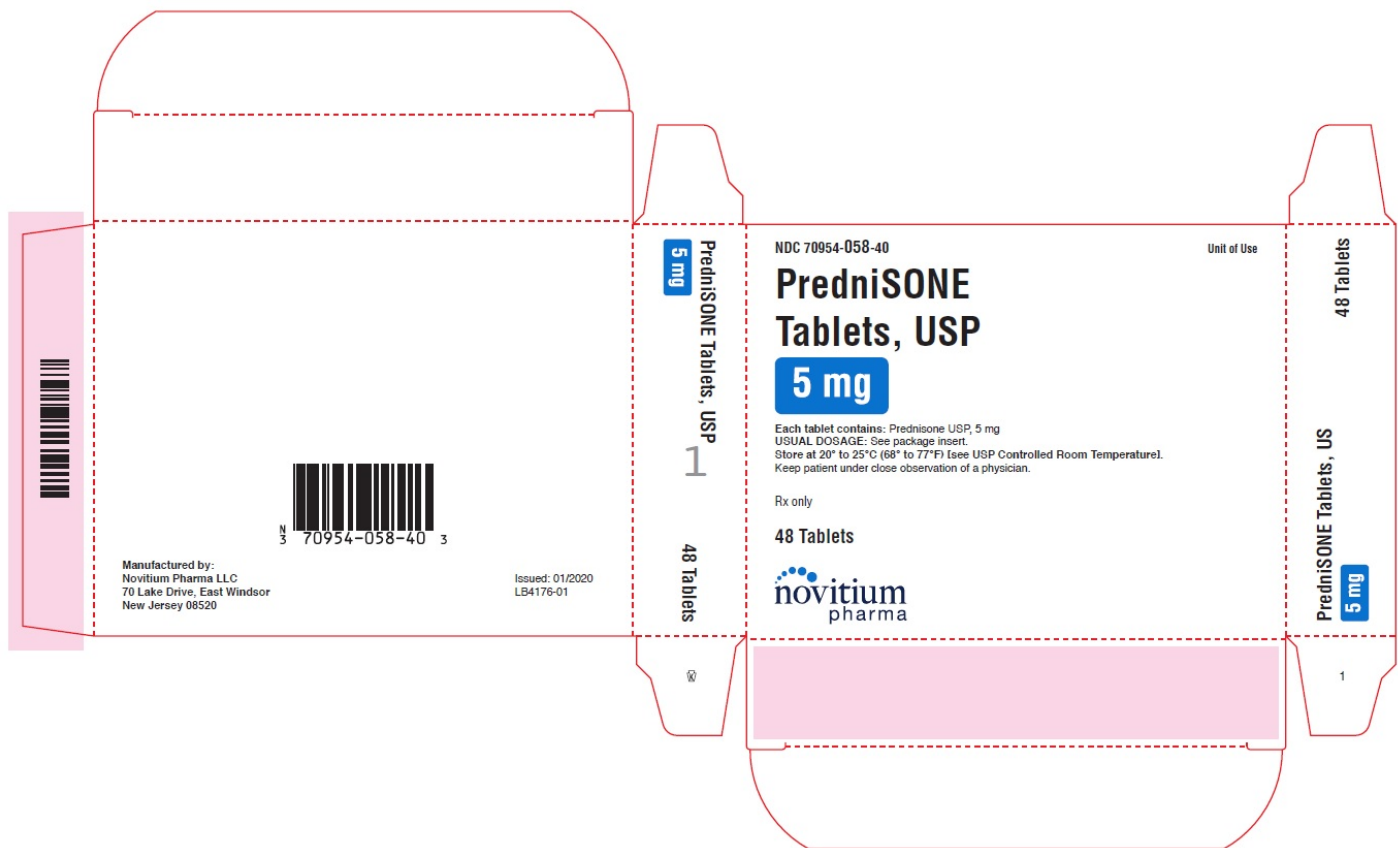
Gently peel back outer layer at TAB before pushing tablet out of foil.
Manufactured by: Novitium Pharma LLC, E. Windsor, NJ-08520

Take 1
tablet
before
breakfast.

**6TH
DAY**



Lot# X00000X
Exp: YYY/MMM



PredniSONE Tablets, USP 10 mg

PredniSONE Tablets, USP 10 mg 100 counts



PredniSONE Tablets, USP 10 mg 1000 counts

NDC 70954-059-20

1,000 Tablets

PredniSONE Tablets, USP

10 mg

Each tablet contains 10 mg of prednisone, USP.



Rx only

Usual Dosage: See accompanying package insert for complete prescribing information.

Store at 20°C to 25°C (68°F to 77°F). [See USP Controlled Room Temperature].

Protect from moisture.

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

Keep container tightly closed.

This package is child-resistant.

Keep this and all medications out of the reach of children.

Manufactured by:
Novitium Pharma LLC
70 Lake Drive, East Windsor
New Jersey 08520

Revised: 03/19

LB4091-01



NO VARNISH

PredniSONE Tablets, USP 10 mg Blister Packs (Unit-of-Use 21 Tablets)

TAB

PredniSONE Tablets, USP 10 mg
Gently peel back outer layer at TAB before pushing tablet out of foil.
Dosage Directions (*see Additional Instructions below)

Unit of Use
21 Tablets

Do NOT discard daily Dosage Directions

1ST DAY

Take 2 tablets before breakfast.

Take 1 tablet after lunch.

Take 1 tablet after supper.

Take 2 tablets at bedtime.

TAB

2ND DAY

Take 1 tablet before breakfast.

Take 1 tablet after lunch.

Take 1 tablet after supper.

Take 2 tablets at bedtime.

PredniSONE Tablets, USP 10 mg
LB4574-04
Rev: 09/23

TAB

3RD DAY

Take 1 tablet before breakfast.

Take 1 tablet after lunch.

Take 1 tablet after supper.

Take 1 tablet at bedtime.

TAB

4TH DAY

Take 1 tablet before breakfast.

Take 1 tablet after lunch.

Take 1 tablet at bedtime.

TAB

5TH DAY

Take 1 tablet before breakfast.

Take 1 tablet at bedtime.

TAB

***Additional Instructions:** Unless otherwise directed by your physician, all six (6) tablets in the row labeled 1ST DAY should be taken the day you receive your prescription. If it is received late in the day, take two tablets every hour for the first day only, then follow directions as printed.

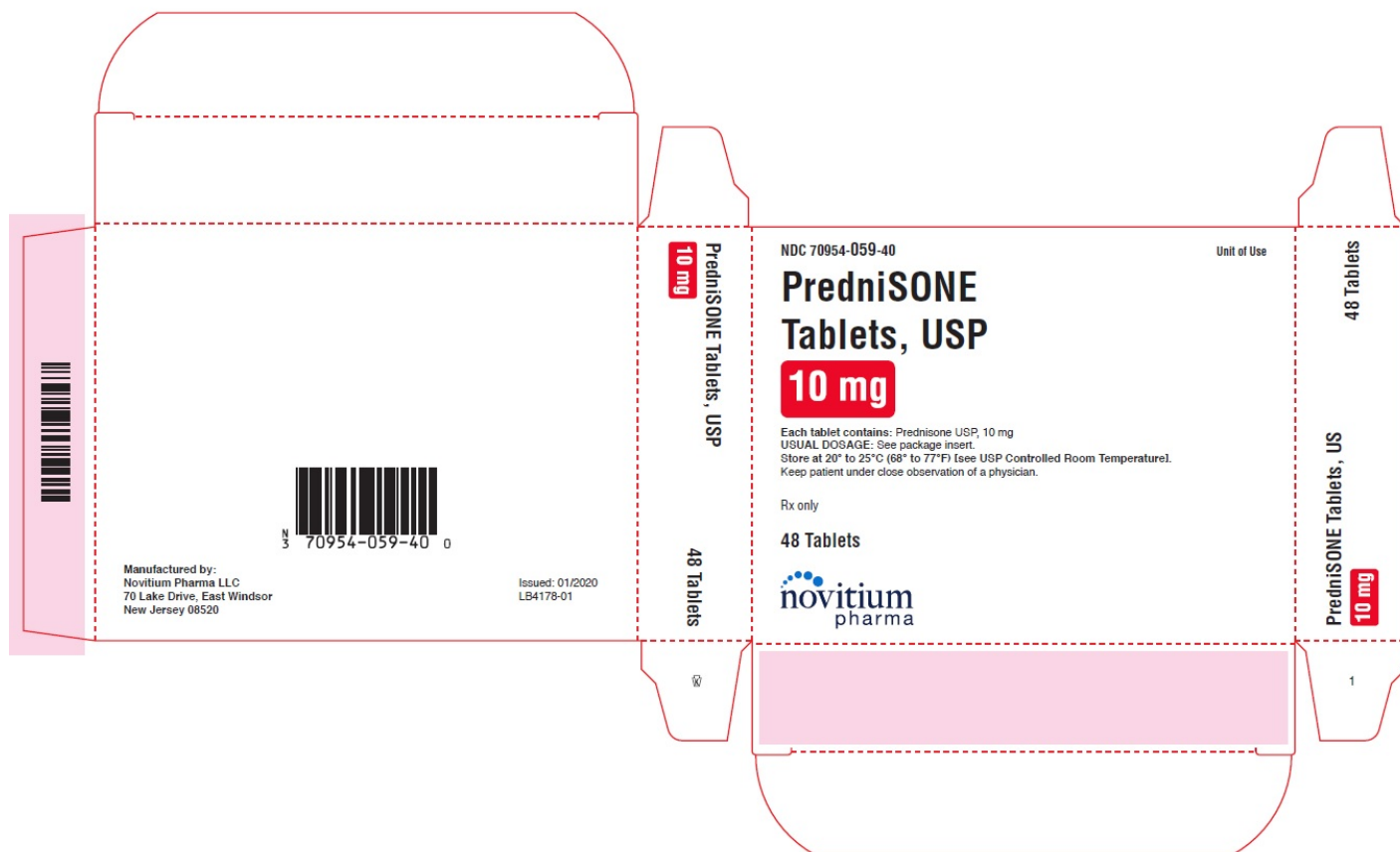
Gently peel back outer layer at TAB before pushing tablet out of foil.
Manufactured by: Novitium Pharma LLC, E. Windsor, NJ-08520

6TH DAY

Take 1 tablet before breakfast.

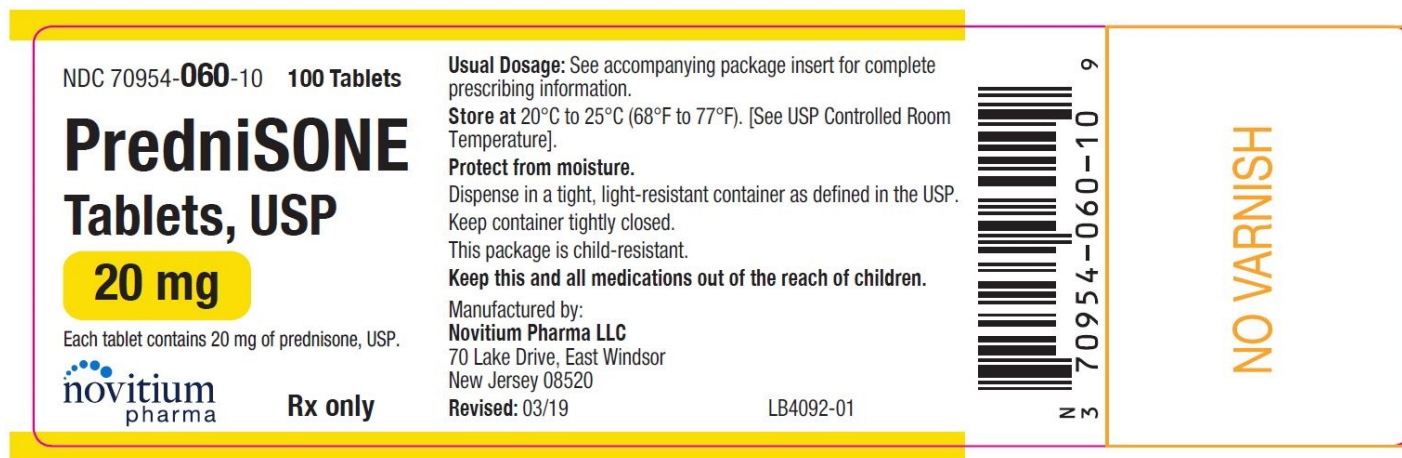


Lot # X00000X
Exp: YY/YY/MM



PredniSONE Tablets, USP 20 mg

PredniSONE Tablets, USP 20 mg 100 counts



PredniSONE Tablets, USP 20 mg 500 counts

NDC 70954-060-20

500 Tablets

PredniSONE Tablets, USP

20 mg

Each tablet contains 20 mg of prednisone, USP.



Rx only

Usual Dosage: See accompanying package insert for complete prescribing information.

Store at 20°C to 25°C (68°F to 77°F). [See USP Controlled Room Temperature].

Protect from moisture.

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

Keep container tightly closed.

This package is child-resistant.

Keep this and all medications out of the reach of children.

Manufactured by:
Novitium Pharma LLC
70 Lake Drive, East Windsor
New Jersey 08520

Revised: 03/19

LB4100-01



N 3

70954-060-20 8

NO VARNISH

PredniSONE Tablets, USP 20 mg 1000 counts

NDC 70954-060-30

1000 Tablets

PredniSONE Tablets, USP

20 mg

Each tablet contains 20 mg of prednisone, USP.



Rx only

Usual Dosage: See accompanying package insert for complete prescribing information.

Store at 20°C to 25°C (68°F to 77°F). [See USP Controlled Room Temperature].

Protect from moisture.

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

Keep container tightly closed.

This package is child-resistant.

Keep this and all medications out of the reach of children.

Manufactured by:
Novitium Pharma LLC
70 Lake Drive, East Windsor
New Jersey 08520

Issued: 06/19

LB4093-00



N 3

70954-060-30 7

NO VARNISH

PredniSONE Tablets, USP 50 mg

PredniSONE Tablets, USP 50 mg 100 counts

NDC 70954-061-10100 Tablets

PredniSONE

Tablets, USP

50 mg

Each tablet contains 50 mg of prednisone, USP.

novitium

pharma

Rx only

Usual Dosage: See accompanying package insert for complete prescribing information.

Store at 20°C to 25°C (68°F to 77°F). [See USP Controlled Room Temperature].

Protect from moisture.

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

Keep container tightly closed.

This package is child-resistant.

Keep this and all medications out of the reach of children.

Manufactured by:
Novitium Pharma LLC
70 Lake Drive, East Windsor
New Jersey 08520

Revised: 03/19

LB4094-01

N 3

70954-061-10 6

NO VARNISH

PREDNISONE

prednisone tablet

| Product Information | | | |
|--|-------------------------|--------------------|---------------|
| Product Type | HUMAN PRESCRIPTION DRUG | Item Code (Source) | NDC:70954-057 |
| Route of Administration | ORAL | | |
| Active Ingredient/Active Moiety | | | |
| Ingredient Name | | Basis of Strength | Strength |
| PREDNISONE (UNII: VB0R961HZT) (PREDNISONE - UNII:VB0R961HZT) | | PREDNISONE | 2.5 mg |
| Inactive Ingredients | | | |
| Ingredient Name | | | Strength |
| LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X) | | | |
| CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U) | | | |
| STARCH, CORN (UNII: O8232NY3SJ) | | | |
| SODIUM LAURYL SULFATE (UNII: 368GB5141J) | | | |
| MAGNESIUM STEARATE (UNII: 70097M6I30) | | | |
| SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2) | | | |
| Product Characteristics | | | |
| Color | WHITE | Score | 2 pieces |
| Shape | ROUND | Size | 5mm |
| Flavor | | Imprint Code | 057 |
| Contains | | | |
| Packaging | | | |
| | | Marketing Start | Marketing End |

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:70954-057-10 | 100 in 1 BOTTLE; Type 0: Not a Combination Product | 11/15/2019 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| ANDA | ANDA211575 | 11/15/2019 | |

| | | | | |
|--|------------------|--|----------------------|--------------------|
| PREDNISONE | | | | |
| prednisone tablet | | | | |
| | | | | |
| Product Information | | | | |
| Product Type | | HUMAN PRESCRIPTION DRUG | Item Code (Source) | |
| Route of Administration | | ORAL | NDC:70954-058 | |
| | | | | |
| Active Ingredient/Active Moiety | | | | |
| Ingredient Name | | | Basis of Strength | Strength |
| PREDNISONE (UNII: VB0R961HZT) (PREDNISONE - UNII:VB0R961HZT) | | | PREDNISONE | 5 mg |
| | | | | |
| Inactive Ingredients | | | | |
| Ingredient Name | | | | Strength |
| LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X) | | | | |
| CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U) | | | | |
| STARCH, CORN (UNII: O8232NY3SJ) | | | | |
| SODIUM LAURYL SULFATE (UNII: 368GB5141J) | | | | |
| MAGNESIUM STEARATE (UNII: 70097M6I3O) | | | | |
| SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2) | | | | |
| | | | | |
| Product Characteristics | | | | |
| Color | WHITE | Score | 2 pieces | |
| Shape | ROUND | Size | 6mm | |
| Flavor | | Imprint Code | 058 | |
| Contains | | | | |
| | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:70954-058-10 | 100 in 1 BOTTLE; Type 0: Not a Combination Product | 11/15/2019 | |
| 2 | NDC:70954- | 1000 in 1 BOTTLE; Type 0: Not a Combination | 11/15/2019 | |

| | | | | |
|---|------------------|---|------------|--|
| 2 | 058-20 | Product | 11/15/2019 | |
| 3 | NDC:70954-058-30 | 1 in 1 BOX | 05/28/2020 | |
| 3 | | 21 in 1 BLISTER PACK; Type 0: Not a Combination Product | | |
| 4 | NDC:70954-058-40 | 1 in 1 BOX | 05/28/2020 | |
| 4 | | 48 in 1 BLISTER PACK; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| ANDA | ANDA211575 | 11/15/2019 | |

PREDNISONE

prednisone tablet

Product Information

| | | | |
|-------------------------|-------------------------|--------------------|---------------|
| Product Type | HUMAN PRESCRIPTION DRUG | Item Code (Source) | NDC:70954-059 |
| Route of Administration | ORAL | | |

Active Ingredient/Active Moiety

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

Inactive Ingredients

| Ingredient Name | Strength |
|--|----------|
| LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X) | |
| CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U) | |
| STARCH, CORN (UNII: O8232NY3SJ) | |
| SODIUM LAURYL SULFATE (UNII: 368GB5141J) | |
| MAGNESIUM STEARATE (UNII: 70097M6I3O) | |
| SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2) | |

Product Characteristics

| | | | |
|----------|-------|--------------|----------|
| Color | WHITE | Score | 2 pieces |
| Shape | ROUND | Size | 6mm |
| Flavor | | Imprint Code | 059 |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:70954-059-10 | 100 in 1 BOTTLE; Type 0: Not a Combination Product | 11/15/2019 | |
| 2 | NDC:70954-059-20 | 1000 in 1 BOTTLE; Type 0: Not a Combination Product | 11/15/2019 | |
| 3 | NDC:70954-059-30 | 1 in 1 BOX | 05/28/2020 | |
| 3 | | 21 in 1 BLISTER PACK; Type 0: Not a Combination Product | | |
| 4 | NDC:70954-059-40 | 1 in 1 BOX | 05/28/2020 | |
| 4 | | 48 in 1 BLISTER PACK; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| ANDA | ANDA211575 | 11/15/2019 | |

PREDNISONE

prednisone tablet

Product Information

| | | | |
|-------------------------|-------------------------|--------------------|---------------|
| Product Type | HUMAN PRESCRIPTION DRUG | Item Code (Source) | NDC:70954-060 |
| Route of Administration | 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 |
|---|----------|
| LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X) | |
| CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U) | |
| SODIUM LAURYL SULFATE (UNII: 368GB5141J) | |
| MAGNESIUM STEARATE (UNII: 70097M6I30) | |
| SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2) | |
| STARCH, CORN (UNII: O8232NY3SJ) | |

Product Characteristics

| | | | |
|--------|-------|--------------|----------|
| Color | WHITE | Score | 2 pieces |
| Shape | ROUND | Size | 8mm |
| Flavor | | Imprint Code | 060 |

Contains**Packaging**

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:70954-060-10 | 100 in 1 BOTTLE; Type 0: Not a Combination Product | 11/15/2019 | |
| 2 | NDC:70954-060-20 | 500 in 1 BOTTLE; Type 0: Not a Combination Product | 11/15/2019 | |
| 3 | NDC:70954-060-30 | 1000 in 1 BOTTLE; Type 0: Not a Combination Product | 11/15/2019 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| ANDA | ANDA211575 | 11/15/2019 | |

PREDNISONE

prednisone tablet

Product Information

| | | | |
|-------------------------|-------------------------|--------------------|---------------|
| Product Type | HUMAN PRESCRIPTION DRUG | Item Code (Source) | NDC:70954-061 |
| Route of Administration | ORAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-------------------|----------|
| PREDNISONE (UNII: VB0R961HZT) (PREDNISONE - UNII:VB0R961HZT) | PREDNISONE | 50 mg |

Inactive Ingredients

| Ingredient Name | Strength |
|---|----------|
| LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X) | |
| CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U) | |
| SODIUM LAURYL SULFATE (UNII: 368GB5141J) | |
| MAGNESIUM STEARATE (UNII: 70097M6I30) | |
| STARCH, CORN (UNII: O8232NY3SJ) | |
| SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2) | |

Product Characteristics

| | | | |
|----------|-------|--------------|----------|
| Color | WHITE | Score | 2 pieces |
| Shape | ROUND | Size | 10mm |
| Flavor | | Imprint Code | 061 |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:70954-061-10 | 100 in 1 BOTTLE; Type 0: Not a Combination Product | 11/15/2019 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| ANDA | ANDA211575 | 11/15/2019 | |

Labeler - ANI Pharmaceuticals, Inc. (145588013)

Establishment

| Name | Address | ID/FEI | Business Operations |
|---------------------|---------|-----------|---|
| Novitium Pharma LLC | | 080301870 | MANUFACTURE(70954-057, 70954-058, 70954-059, 70954-060, 70954-061) , PACK(70954-057, 70954-058, 70954-059, 70954-060, 70954-061) |

Revised: 1/2025

ANI Pharmaceuticals, Inc.