**PREDNISONE - prednisone tablet**
**Aurobindo Pharma Limited**

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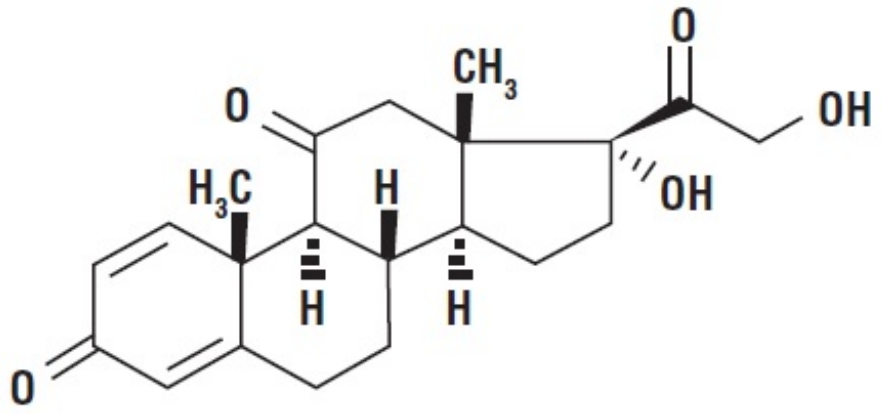
**Prednisone Tablets, USP**

**Rx only**

## DESCRIPTION

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 structure.:




Molecular formula: $C_{21}H_{26}O_5$

Prednisone USP is a white to partially white, odorless, crystalline powder and has a molecular weight of 358.43. It melts at about 230°C with some decomposition.

Prednisone USP is very slightly soluble in water; slightly soluble in alcohol, chloroform, dioxane, and methanol. Prednisone tablets USP contain 1 mg prednisone, USP.

The inactive ingredients for prednisone tablets USP include: D&C yellow No.10 aluminum lake, FD&C yellow # 6 aluminum lake, lactose monohydrate, magnesium stearate, microcrystalline cellulose, pregelatinized starch (maize), and sodium starch glycolate.

Meets USP Dissolution Test 2.

## ACTIONS

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

***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; posttraumatic 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 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, 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 anti-tuberculous 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 subject to any 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 doses, because of possible hazards of neurological complications and a lack of antibody response.*

**PRECAUTIONS: 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.

**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 in patients with hypothyroidism as 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.

## 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.

***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 of 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 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 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, 1 mg** are beige colored, round, biconvex tablets, scored on one side and “PI”, “1” on other side. They are supplied as follows:

| | |
|---|---|
| Bottles of 100 | NDC 59651-484-01 |
| Bottles of 1,000 | NDC 59651-484-99 |
| 10x10 Unit-dose Tablets | NDC 59651-484-78 |

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

Dispense in a tight, child-resistant container as defined in the USP/NF.

PROTECT FROM MOISTURE.

Distributed by:
**Aurobindo Pharma USA, Inc.**
279 Princeton-Hightstown Road
East Windsor, NJ 08520

Manufactured by:
**Aurobindo Pharma Limited**
Hyderabad-500 032, India

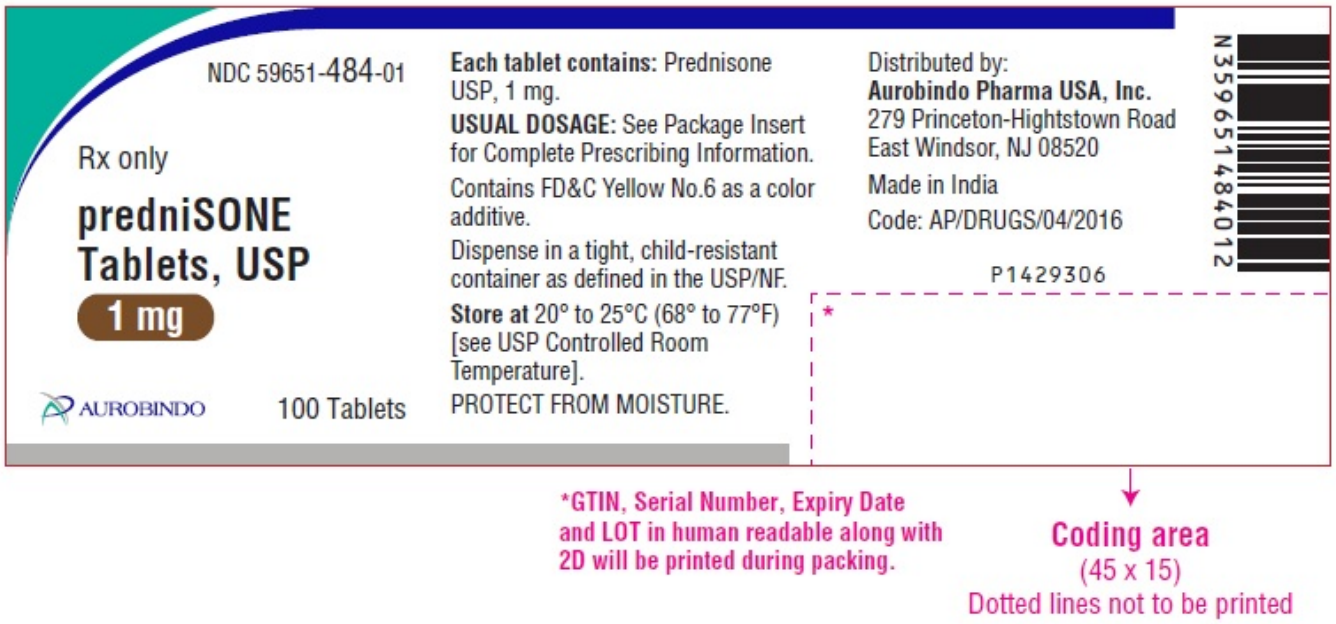
Revised: 02/2024

## PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - 1 mg (100 Tablet Bottle)

NDC 59651-484-01

Rx only
**predniSONE**
**Tablets, USP**
**1 mg**

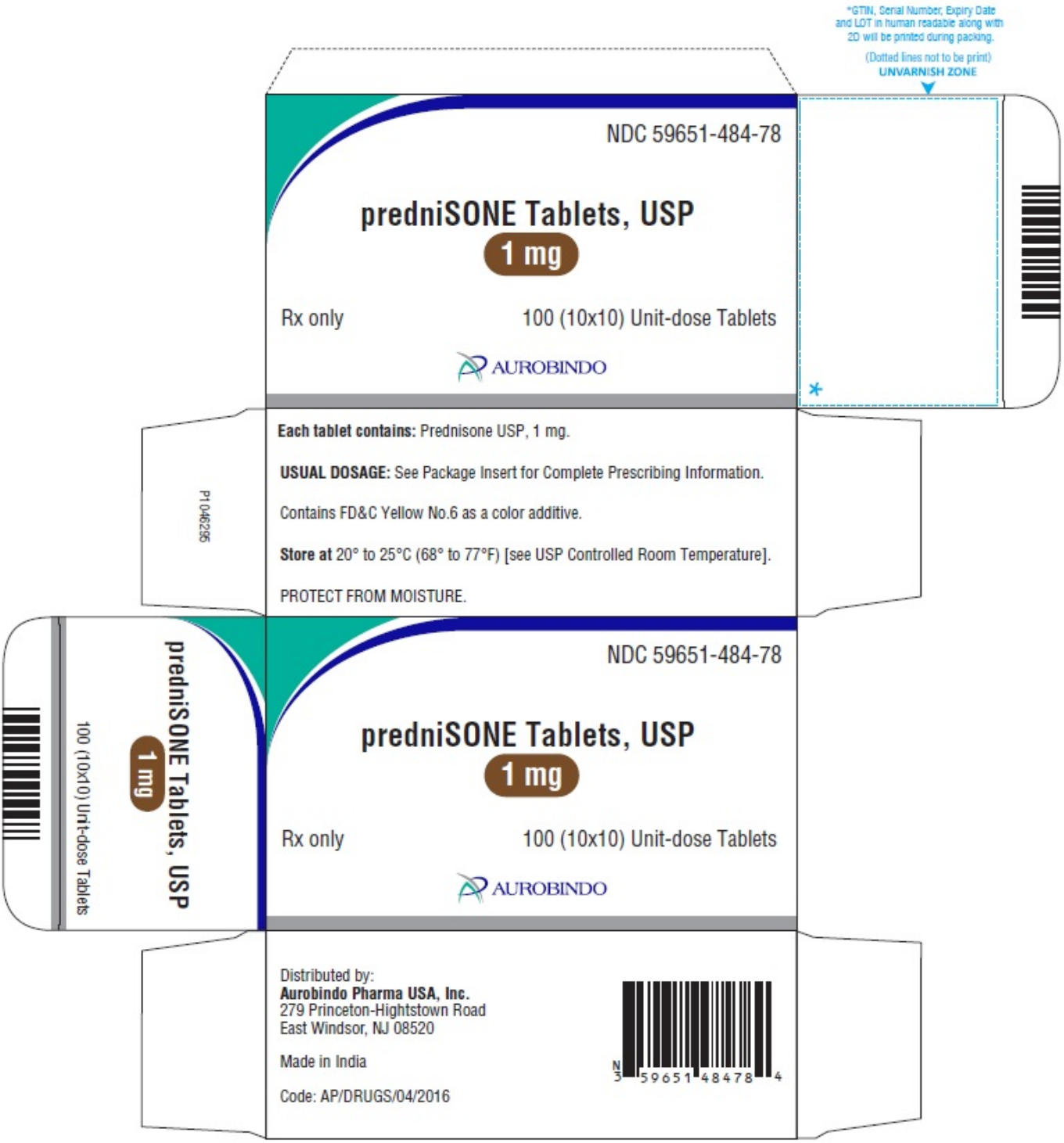
**AUROBINDO** 100 Tablets




**PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - 1 mg 100(10x10) Unit-dose Tablets**

NDC 59651-484-78

**predniSONE Tablets, USP**
**1 mg**
Rx only 100 (10x10) Unit-dose Tablets
**AUROBINDO**




# PREDNISONE

prednisone tablet

| Product Information | | | |
|---|---|---|---|
| **Product Type** | HUMAN PRESCRIPTION DRUG | **Item Code (Source)** | NDC:59651-484 |
| **Route of Administration** | ORAL | | |

## Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|---|---|
| **PREDNISONE** (UNII: VB0R961HZT) (PREDNISONE - UNII:VB0R961HZT) | PREDNISONE | 1 mg |

## Inactive Ingredients

| Ingredient Name | Strength |
|---|---|
| **D&C YELLOW NO. 10 ALUMINUM LAKE** (UNII: CQ3XH3DET6) | |
| **FD&C YELLOW NO. 6** (UNII: H77VEI93A8) | |
| **LACTOSE MONOHYDRATE** (UNII: EWQ57Q8I5X) | |
| **MAGNESIUM STEARATE** (UNII: 70097M6I30) | |
| **MICROCRYSTALLINE CELLULOSE 101** (UNII: 7T9FYH5QMK) | |
| **STARCH, CORN** (UNII: O8232NY3SJ) | |
| **SODIUM STARCH GLYCOLATE TYPE A** (UNII: H8AV0SQX4D) | |

## Product Characteristics

| | | | |
|---|---|---|---|
| **Color** | BROWN (Beige) | **Score** | 2 pieces |
| **Shape** | ROUND (Biconvex) | **Size** | 7mm |
| **Flavor** | | **Imprint Code** | PI;1 |
| **Contains** | | | |

## Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| **1** | NDC:59651-484-01 | 100 in 1 BOTTLE; Type 0: Not a Combination Product | 11/16/2021 | |
| **2** | NDC:59651-484-99 | 1000 in 1 BOTTLE; Type 0: Not a Combination Product | 11/16/2021 | |
| **3** | NDC:59651-484-78 | 10 in 1 CARTON | 11/16/2021 | |
| **3** | | 10 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 | ANDA215671 | 11/16/2021 | |

## Labeler - Aurobindo Pharma Limited (650082092)

## Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---|---|---|
| APL HEALTHCARE LIMITED | | 650918514 | ANALYSIS(59651-484) , MANUFACTURE(59651-484) |