

METHYLPREDNISOLONE- methylprednisolone tablet

BluePoint Laboratories

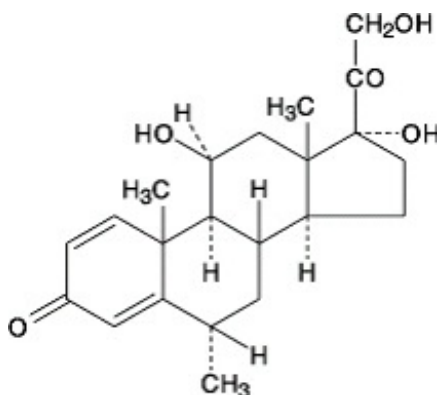
METHYLPREDNISOLONE TABLETS, USP

Rx Only

DESCRIPTION

Methylprednisolone Tablets, USP contain methylprednisolone which is a glucocorticoid. Glucocorticoids are adrenocortical steroids, both naturally occurring and synthetic, which are readily absorbed from the gastrointestinal tract. Methylprednisolone occurs as a white to practically white, odorless, crystalline powder. It is sparingly soluble in alcohol, in dioxane, and in methanol, slightly soluble in acetone, and in chloroform, and very slightly soluble in ether. It is practically insoluble in water.

The chemical name for methylprednisolone is pregna-1,4-diene-3,20-dione, 11, 17, 21-trihydroxy-6- methyl-, (6 α ,11 β)- and the molecular weight is 374.48. The structural formula is represented below:



C₂₂H₃₀O₅

Methylprednisolone Tablets, USP for oral administration, are available as scored tablets in the following strength: 4 mg, 8 mg, 16 mg, and 32 mg. In addition each tablet contains the following inactive ingredients: colloidal silicon dioxide, lactose anhydrous (4 mg and 8 mg), lactose monohydrate (16 mg and 32 mg), magnesium stearate, microcrystalline cellulose, pregelatinized starch, sodium lauryl sulfate 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 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 AND USAGE

Methylprednisolone Tablets are 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).

Congenital adrenal hyperplasia

Nonsuppurative thyroiditis

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:

Rheumatoid arthritis, including juvenile rheumatoid arthritis (selected cases may require low-dose maintenance therapy)

Ankylosing spondylitis

Acute and subacute bursitis

Synovitis of osteoarthritis

Acute nonspecific tenosynovitis

Post-traumatic osteoarthritis

Psoriatic arthritis

Epicondylitis

Acute gouty arthritis

3.Collagen Diseases

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

Systemic lupus erythematosus

Systemic dermatomyositis (polymyositis)

Acute rheumatic carditis

4.Dermatologic Diseases

Bullous dermatitis herpetiformis

Severe erythema multiforme (Stevens-Johnson syndrome)

Severe seborrheic dermatitis

Exfoliative dermatitis

Mycosis fungoides

Pemphigus

Severe psoriasis

5.Allergic States

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

Seasonal or perennial allergic rhinitis

Drug hypersensitivity reactions

Serum sickness

Contact dermatitis

Bronchial asthma

Atopic dermatitis

6.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

Keratitis

Optic neuritis

Allergic conjunctivitis

Chorioretinitis

Iritis and iridocyclitis

7.Respiratory Diseases

Symptomatic sarcoidosis

Berylliosis

Loeffler's syndrome not manageable by other means

Fulminating or disseminated pulmonary tuberculosis when used concurrently with appropriate antituberculous chemotherapy

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:

Leukemias and lymphomas in adults

Acute leukemia of childhood

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:

Ulcerative colitis

Regional enteritis

12.Nervous System

Acute exacerbations of multiple sclerosis

13.Miscellaneous

Tuberculous meningitis with subarachnoid block or impending block when used concurrently with appropriate antituberculous chemotherapy.

Trichinosis with neurologic or myocardial involvement.

CONTRAINDICATIONS

Systemic fungal infections and known hypersensitivity to components.

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.

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 child-bearing 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.

The use of Methylprednisolone 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.

Children who are on immunosuppressant drugs are more susceptible to infections than healthy children. Chickenpox and measles, for example, can have a more serious or even fatal course in children on immunosuppressant corticosteroids. In such children, or in adults who have not had these diseases, particular care should be taken to avoid exposure. If exposed, therapy with varicella zoster immune globuline (VZIG) or pooled intravenous immunoglobulin (IVIG), as appropriate, may be indicated. If chickenpox develops, treatment with antiviral agents may be considered.

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.

Caution is required in patients with systemic sclerosis because an increased incidence of scleroderma renal crisis has been observed with corticosteroids, including methylprednisolone.

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.

In post marketing experience, tumor lysis syndrome (TLS) has been reported in patients with malignancies, including hematological malignancies and solid tumors, following the use of systemic corticosteroids alone or in combination with other chemotherapeutic agents. Patients at high risk of TLS, such as patients with tumors that have a high proliferative rate, high tumor burden and high sensitivity to cytotoxic agents, should be monitored closely and appropriate precautions should be taken.

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 the Patient

Persons 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

Fluid and Electrolyte Disturbances

- Sodium retention
- Congestive heart failure in susceptible patients

- Hypertension
- Fluid retention
- Potassium loss
- Hypokalemic alkalosis

Musculoskeletal

- Muscle weakness
- Loss of muscle mass
- Steroid myopathy
- 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
- Petechiae and ecchymoses
- May suppress reactions to skin tests
- Thin fragile skin
- Facial erythema
- Increased sweating

Neurological

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

Endocrine

- 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
- Menstrual irregularities
- 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

The following additional reactions have been reported following oral as well as parenteral therapy:

Urticaria and other allergic, anaphylactic or hypersensitivity reactions.

DOSAGE AND ADMINISTRATION

The initial dosage of Methylprednisolone Tablets may vary from 4 mg to 48 mg of methylprednisolone 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, Methylprednisolone 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 methylprednisolone 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 (4 mg of methylprednisolone is equivalent to 5 mg of prednisolone).

ADT[®] (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 reestablishment 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 adrenal cortical 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 adrenal cortical 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 adrenal cortical 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 six 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 adrenal cortical suppression for two or more days. Other corticoids, including methylprednisolone, hydrocortisone, prednisone, and prednisolone, are considered to be short acting (producing adrenal cortical suppression for $1\frac{1}{4}$ to $1\frac{1}{2}$ 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 ADT should not encourage the indiscriminate use of steroids.
- 2) ADT is a therapeutic technique primarily designed for patients in whom long-term

pharmacologic corticoid therapy is anticipated.

3. 3) In less severe disease processes in which corticoid therapy is indicated, it may be possible to initiate treatment with ADT. 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.
4. Once control has been established, two courses are available: (a) change to ADT 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.
5. 4) Because of the advantages of ADT, it may be desirable to try patients on this form of therapy who
6. have been on daily corticoids for long periods of time (e.g., patients with rheumatoid arthritis). Since
7. these patients may already have a suppressed HPA axis, establishing them on ADT may be difficult
8. and not always successful. However, it is recommended that regular attempts be made to change
9. them over. It may be helpful to triple or even quadruple the daily maintenance dose and administer
10. this every other day rather than just doubling the daily dose if difficulty is encountered. Once the
11. patient is again controlled, an attempt should be made to reduce this dose to a minimum.
12. 5) As indicated above, certain corticosteroids, because of their prolonged suppressive effect on adrenal
13. activity, are not recommended for alternate day therapy (e.g., dexamethasone and betamethasone).
14. 6) The maximal activity of the adrenal cortex is between 2 am and 8 am, and it is minimal between 4
15. pm and midnight. Exogenous corticosteroids suppress adrenocortical activity the least, when given
16. at the time of maximal activity (am).
17. 7) In using ADT it is important, as in all therapeutic situations to individualize and tailor the therapy to
18. each patient. Complete control of symptoms will not be possible in all patients. An explanation of the
19. benefits of ADT will help the patient to understand and tolerate the possible flare-up in symptoms
20. which may occur in the latter part of the off-steroid day. Other symptomatic therapy may be added
21. or increased at this time if needed.
22. 8) In the event of an acute flare-up of the disease process, it may be necessary to return to a full
23. suppressive daily divided corticoid dose for control. Once control is again established alternate day

24. therapy may be reinstituted.
25. 9) Although many of the undesirable features of corticosteroid therapy can be minimized by ADT, as in
26. any therapeutic situation, the physician must carefully weigh the benefit-risk ratio for each patient in
27. whom corticoid therapy is being considered.

HOW SUPPLIED

Methylprednisolone Tablets, USP are available in the following strength and package size:

4 mg(White, oval-shaped tablets debossed with “TL 001” on one side and quadrisected on the other side.) Bottles of 100 tablets with Child Resistant Closure, NDC 68001-557-00 Unit of use pack (21 tablets) NDC 68001-005-01

8 mg(White, oval shaped tablets debossed with “TL” and “002” on either side of score line on one side and plain on other side.) Bottles of 25 tablets with Child Resistant Closure, NDC 68001-558-55

16 mg(White, oval shaped tablets debossed with “TL 003” on one side and quadrisected on the other side.) Bottles of 50 tablets with Child Resistant Closure, NDC 68001-559-69

32 mg(White, oval shaped tablets debossed with “TL 015” on one side and bisected on the other side.) Bottles of 25 tablets with Child Resistant Closure, NDC 68001-560-55

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

Manufactured by: **JUBILANT CADISTA PHARMACEUTICALS INC.** Salisbury, MD 21801, USA For BluePoint Laboratories. Rev. 01/2024

Package/Label Display Panel



Package/Label Display Panel

Dosage Directions**To remove tablet, press from this side**

1st day

Take 2 tablets before breakfast, 1 tablet after lunch and supper, and 2 tablets at bedtime.

2nd day

Take 1 tablet before breakfast, 1 tablet after lunch and supper, and 2 tablets at bedtime.

3rd day

Take 1 tablet before breakfast and 1 tablet after lunch, after supper, and at bedtime.

4th day

Take 1 tablet before breakfast, after lunch, and at bedtime.

5th day

Take 1 tablet before breakfast and at bedtime.

6th day

Take 1 tablet before breakfast.

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, even though you may not receive it until late in the day. All six (6) tablets may be taken immediately as a single dose, or may be divided into two or three doses and taken at intervals between the time you receive the medicine and your regular bedtime.

Methylprednisolone Tablets, USP 4 mg Unit of Use 21 Tablets**Package/Label Display Panel**

PACKAGE NOT CHILD RESISTANT

N
3
68001
00501
2

Methylprednisolone Tablets, USP 4 mg

Unit of Use

21 Tablets

Rx only

Package/Label Display Panel

Rev. 11/22

N
3
68001
155700
9

See prescribing information for complete product information.

Dispense in tight, light resistant container.

Keep patient under close observation of a physician.

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

Manufactured by:
Jubilant Cadista Pharmaceuticals Inc.
Salisbury, MD 21801, USA
For BluePoint Laboratories.

NDC 68001-557-00

MethylPREDNISolone
Tablets, USP

4mg

100 Tablets

TL 001

50000003660

NVZ AREA
SIZE : 1.88X 0.78

Package/Label Display Panel

Rev. 11/22

6

5855

68001

3

See prescribing information for complete product information.

Dispense in tight, light resistant container.

Keep patient under close observation of a physician.

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

Manufactured by:
Jubilant Cadista Pharmaceuticals Inc.
Salisbury, MD 21801, USA
For BluePoint Laboratories.

NDC 68001-558-55

Rx Only

MethylPREDNISolone

Tablets, USP

8mg

25 Tablets

TL 002

50000003711

NVZ AREA

SIZE : 1.88X 0.78

Package/Label Display Panel

Rev. 11/22

0

5969

68001

3

See prescribing information for complete product information.

Dispense in tight, light resistant container.

Keep patient under close observation of a physician.

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

Manufactured by:
Jubilant Cadista Pharmaceuticals Inc.
Salisbury, MD 21801, USA
For BluePoint Laboratories.

NDC 68001-559-69

Rx Only

MethylPREDNISolone

Tablets, USP

16mg

50 Tablets

TL 003

50000003712

NVZ AREA

SIZE : 1.88X 0.78

Package/Label Display Panel

Rev. 11/22

9

56055

68001

3

See prescribing information for complete product information.

Dispense in tight, light resistant container.

Keep patient under close observation of a physician.

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

Manufactured by:
Jubilant Cadista Pharmaceuticals Inc.
Salisbury, MD 21801, USA
For BluePoint Laboratories.

NDC 68001-560-55

Rx Only

MethylPREDNISolone

Tablets, USP

32mg

25 Tablets

TL 015

50000003713

NVZ AREA

SIZE : 1.88X 0.78

METHYLPREDNISOLONE

methylprednisolone tablet

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:68001-005
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name		Basis of Strength
METHYLPREDNISOLONE (UNII: X4W7ZR7023) (METHYLPREDNISOLONE - UNII:X4W7ZR7023)		METHYLPREDNISOLONE 4 mg

Inactive Ingredients	
Ingredient Name	Strength
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
STARCH, CORN (UNII: O8232NY3SJ)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	

Product Characteristics			
Color	white	Score	4 pieces
Shape	OVAL (Oval)	Size	8mm
Flavor		Imprint Code	TL001
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68001-005-01	21 in 1 BLISTER PACK; Type 0: Not a Combination Product	08/02/2013	03/31/2026

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA040189	08/02/2013	03/31/2026

METHYLPREDNISOLONE

methylprednisolone tablet

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:68001-557
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
METHYLPREDNISOLONE (UNII: X4W7ZR7023) (METHYLPREDNISOLONE - UNII:X4W7ZR7023)	METHYLPREDNISOLONE	4 mg

Inactive Ingredients	
Ingredient Name	Strength
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
STARCH, CORN (UNII: O8232NY3SJ)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	

Product Characteristics			
Color	white	Score	4 pieces
Shape	OVAL (Oval)	Size	8mm
Flavor		Imprint Code	TL001
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68001-557-00	100 in 1 BOTTLE; Type 0: Not a Combination Product	01/31/2023	03/31/2026

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA040189	01/31/2023	03/31/2026

METHYLPREDNISOLONE			
methylprednisolone tablet			
Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:68001-558

Route of Administration		ORAL		
Active Ingredient/Active Moiety				
Ingredient Name		Basis of Strength	Strength	
METHYLPREDNISOLONE (UNII: X4W7ZR7023) (METHYLPREDNISOLONE - UNII:X4W7ZR7023)		METHYLPREDNISOLONE	8 mg	
Inactive Ingredients				
Ingredient Name			Strength	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)				
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)				
MAGNESIUM STEARATE (UNII: 70097M6I30)				
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)				
SODIUM LAURYL SULFATE (UNII: 368GB5141J)				
STARCH, CORN (UNII: O8232NY3SJ)				
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)				
Product Characteristics				
Color	white	Score	2 pieces	
Shape	OVAL (Oval)	Size	10mm	
Flavor		Imprint Code	TL002	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68001-558-55	25 in 1 BOTTLE; Type 0: Not a Combination Product	01/31/2023	03/31/2026
Marketing Information				
Marketing Category	Application Number or Monograph Citation		Marketing Start Date	Marketing End Date
ANDA	ANDA040189		01/31/2023	03/31/2026

METHYLPREDNISOLONE

methylprednisolone tablet

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:68001-559
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
METHYLPREDNISOLONE (UNII: X4W7ZR7023) (METHYLPREDNISOLONE - UNII:X4W7ZR7023)	METHYLPREDNISOLONE	16 mg

Inactive Ingredients	
Ingredient Name	Strength
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
STARCH, CORN (UNII: O8232NY3SJ)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	

Product Characteristics			
Color	white	Score	4 pieces
Shape	OVAL (Oval)	Size	10mm
Flavor		Imprint Code	TL003;
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68001-559-69	50 in 1 BOTTLE; Type 0: Not a Combination Product	01/31/2023	12/31/2025

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA040189	01/31/2023	12/31/2025

METHYLPREDNISOLONE			
methylprednisolone tablet			
Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:68001-560
Route of Administration	ORAL		
Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	

METHYLPREDNISOLONE (UNII: X4W7ZR7023) (METHYLPREDNISOLONE - UNII:X4W7ZR7023)	METHYLPREDNISOLONE	32 mg
---	--------------------	-------

Inactive Ingredients

Ingredient Name	Strength
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
STARCH, CORN (UNII: O8232NY3SJ)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	

Product Characteristics

Color	white	Score	2 pieces
Shape	OVAL (Oval)	Size	12mm
Flavor		Imprint Code	TL015;
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68001-560-55	25 in 1 BOTTLE; Type 0: Not a Combination Product	01/31/2023	03/31/2026

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA040189	01/31/2023	03/31/2026

Labeler - BluePoint Laboratories (985523874)

Establishment

Name	Address	ID/FEI	Business Operations
JUBILANT CADISTA PHARMACEUTICALS, INC.		022490515	manufacture(68001-005, 68001-557, 68001-558, 68001-559, 68001-560)