METHYLPREDNISOLONE TABLETS, USP Rx only

DESCRIPTION

Methylprednisolone Tablets 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-, (6α,11β)- and the molecular weight is 374.48. The structural formula is represented below:

![Structural formula of Methylprednisolone](image)

C_{22}H_{30}O_5

Methylprednisolone Tablets, for oral administration, are available as scored tablets in the following strengths: 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 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.

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.

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

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 for insulin or oral hypoglycemic agents in diabetics

Ophthalmic
Posterior subcapsular cataracts
Increased intraocular pressure
Glaucoma
Exophthalmos

Metabolic
Negative nitrogen balance due to protein catabolism

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 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 (Alternative Day Therapy):** Alternative 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 1/4 to 1 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. 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.

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.

4. Because of the advantages of ADT, it may be desirable to try patients on this form of therapy who have been on daily corticoids for long periods of time (eg, patients with rheumatoid arthritis). Since these patients may already have a suppressed HPA axis, establishing them on ADT 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 (eg, 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 ADT 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 ADT 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 reinstituted.

9. Although many of the undesirable features of corticosteroid therapy can be minimized by ADT, 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**

Methylprednisolone Tablets are available in the following strengths and package sizes:

**4mg** (White, oval shaped tablets, debossed with "TL 001" on one side and quadrisected on the other side.)
Bottles of 100: NDC 59746-001-06
Unit of use pack (21 tablets): NDC 59746-001-03

**8mg** (White, oval shaped tablets, debossed with "TL 002", scored on one side and plain on the other side.)
Bottles of 25:NDC 59746-002-04
Bottles of 100:NDC 59746-002-06

16 mg (White, oval shaped tablets, debossed with "TL 003" on one side and quadrisectioned on the other side.)

Bottles of 50:NDC 59746-003-14

32 mg (White, oval shaped tablets, debossed with "TL 015" on one side and bisected on the other side.)

Bottles of 25:NDC 59746-015-04

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

Rx only

Jubilant Cadista Pharmaceuticals Inc.
Salisbury, MD 21801, USA
Revised: 10/2017

PACKAGE LABEL

NDC 59746-001-06

MethylPREDNISolone Tablets, USP

4 mg

CADISTA™

100 Tablets

Rx Only
See package insert for complete product information.

Dispense in tight, light resistant container.

Keep patient under close observation of a physician.

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

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

TL 001
MethyLPREDNISolone Tablets, USP

4 mg

21 Tablets
Unit of Use

Rx Only

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

Keep patient under close observation of a physician.

Each tablet contains 4 mg of methylprednisolone, USP.
Each tablet contains 4 mg of methylprednisolone, USP.

Keep patient under close observation of a physician.

See package insert for complete product information.

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

**Rx only**

**PACKAGE NOT CHILD RESISTANT**
MethylPREDNISolone Tablets, USP

8 mg

CADISTA™

25 Tablets

Rx Only

Rev # 03/17

See package insert for complete product information.

Dispense in tight, light resistant container.

Keep patient under close observation of a physician.

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

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

TL 002
NDC 59746-003-14

MethylPREDNISolone Tablets, USP

16 mg

CADISTA™

50 Tablets

Rx Only

Rev # 03/17

See package insert for complete product information.

Dispense in tight, light resistant container.

Keep patient under close observation of a physician.

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

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

TL 003
NDC 59746-015-04

MethylPREDNISolone Tablets, USP

32 mg

CADISTA™

25 Tablets

Rx Only

Rev # 03/17

See package insert for complete product information.

Dispense in tight, light resistant container.

Keep patient under close observation of a physician.

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

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

TL 015

METHYLPREDNISOLONE
methylprednisolone tablet
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METHYLPREDNISOLONE

methylprednisolone tablet

Product Information

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<td>25 in 1 BOTTLE; Type 0: Not a Combination Product</td>
<td>10/31/1997</td>
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<td>NDC:59746-002-06</td>
<td>100 in 1 BOTTLE; Type 0: Not a Combination Product</td>
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</table>

Marketing Information

<table>
<thead>
<tr>
<th>Marketing Category</th>
<th>Application Number or Monograph Citation</th>
<th>Marketing Start Date</th>
<th>Marketing End Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>ANDA</td>
<td>ANDA040189</td>
<td>10/31/1997</td>
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</tr>
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</table>

METHYLPREDNISOLONE
methylprednisolone tablet

Product Information

<table>
<thead>
<tr>
<th>Product Type</th>
<th>Item Code (Source)</th>
</tr>
</thead>
<tbody>
<tr>
<td>HUMAN PRESCRIPTION DRUG</td>
<td>NDC:59746-003</td>
</tr>
<tr>
<td>ORAL</td>
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</tr>
</tbody>
</table>
### Active Ingredient/Active Moiety

<table>
<thead>
<tr>
<th>Ingredient Name</th>
<th>Basis of Strength</th>
<th>Strength</th>
</tr>
</thead>
<tbody>
<tr>
<td>Methylprednisolone (UNII: X4W7ZR7023) (Methylprednisolone - UNII:X4W7ZR7023)</td>
<td>Methylprednisolone</td>
<td>16 mg</td>
</tr>
</tbody>
</table>

### Inactive Ingredients

<table>
<thead>
<tr>
<th>Ingredient Name</th>
<th>Strength</th>
</tr>
</thead>
<tbody>
<tr>
<td>Silicon Dioxide (UNII: ETJ7Z6XBU4)</td>
<td></td>
</tr>
<tr>
<td>Lactose monohydrate (UNII: EWQ57Q815X)</td>
<td></td>
</tr>
<tr>
<td>Magnesium stearate (UNII: 70097M6I30)</td>
<td></td>
</tr>
<tr>
<td>Cellulose, Microcrystalline (UNII: OP1R32D61U)</td>
<td></td>
</tr>
<tr>
<td>Sodium lauryl sulfate (UNII: 368GB5141J)</td>
<td></td>
</tr>
<tr>
<td>Starch, Corn (UNII: O8232NY3SJ)</td>
<td></td>
</tr>
<tr>
<td>Sodium Starch Glycolate Type A Potato (UNII: 5856J3G2A2)</td>
<td></td>
</tr>
</tbody>
</table>

### Product Characteristics

<table>
<thead>
<tr>
<th>Color</th>
<th>WHITE</th>
<th>Score</th>
<th>4 pieces</th>
</tr>
</thead>
<tbody>
<tr>
<td>Shape</td>
<td>OVAL (Oval)</td>
<td>Size</td>
<td>10mm</td>
</tr>
<tr>
<td>Flavor</td>
<td></td>
<td>Imprint Code</td>
<td>TL003</td>
</tr>
<tr>
<td>Contains</td>
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### Packaging

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<thead>
<tr>
<th>#</th>
<th>Item Code</th>
<th>Package Description</th>
<th>Marketing Start Date</th>
<th>Marketing End Date</th>
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<tbody>
<tr>
<td>1</td>
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<td>50 in 1 BOTTLE; Type 0: Not a Combination Product</td>
<td>10/31/1997</td>
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### Marketing Information

<table>
<thead>
<tr>
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</tbody>
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### METHYLPREDNISOLONE
methylprednisolone tablet

### Product Information

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<th>Product Type</th>
<th>Item Code (Source)</th>
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</thead>
<tbody>
<tr>
<td>HUMAN PRESCRIPTION DRUG</td>
<td>NDC:59746-015</td>
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<tr>
<td>ORAL</td>
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</tbody>
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### Active Ingredient/Active Moiety

<table>
<thead>
<tr>
<th>Ingredient Name</th>
<th>Basis of Strength</th>
<th>Strength</th>
</tr>
</thead>
<tbody>
<tr>
<td>Methylprednisolone (UNII: X4W7ZR7023) (Methylprednisolone - UNII:X4W7ZR7023)</td>
<td>Methylprednisolone</td>
<td>32 mg</td>
</tr>
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### Inactive Ingredients

<table>
<thead>
<tr>
<th>Ingredient Name</th>
<th>Strength</th>
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</thead>
<tbody>
<tr>
<td>Silicon Dioxide (UNII: ETJ7Z6XBU4)</td>
<td></td>
</tr>
<tr>
<td>Lactose monohydrate (UNII: EWQ57Q815X)</td>
<td></td>
</tr>
<tr>
<td>Magnesium stearate (UNII: 70097M6I30)</td>
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</tr>
<tr>
<td>Cellulose, Microcrystalline (UNII: OP1R32D61U)</td>
<td></td>
</tr>
<tr>
<td>Sodium lauryl sulfate (UNII: 368GB5141J)</td>
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</tr>
<tr>
<td>Starch, Corn (UNII: O8232NY3SJ)</td>
<td></td>
</tr>
<tr>
<td>Sodium Starch Glycolate Type A Potato (UNII: 5856J3G2A2)</td>
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### Product Characteristics

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Description</th>
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<tbody>
<tr>
<td>Color</td>
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</tr>
<tr>
<td>Shape</td>
<td>OVAL (Oval)</td>
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<tr>
<td>Size</td>
<td>12mm</td>
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<td>Imprint Code</td>
<td>TL015</td>
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### Packaging

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<td>25 in 1 BOTTLE; Type 0: Not a Combination Product</td>
<td>10/31/1997</td>
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</tr>
</tbody>
</table>

### Labeler

- **JUBILANT CADISTA PHARMACEUTICALS INC.** (022490515)

### Establishment

<table>
<thead>
<tr>
<th>Name</th>
<th>Address</th>
<th>ID/FEI</th>
<th>Business Operations</th>
</tr>
</thead>
<tbody>
<tr>
<td>JUBILANT CADISTA PHARMACEUTICALS INC.</td>
<td></td>
<td>022490515</td>
<td>manufacture(59746-001, 59746-002, 59746-003, 59746-015)</td>
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</tbody>
</table>

Revised: 10/2017

JUBILANT CADISTA PHARMACEUTICALS INC.