METHYLprednisolone Tablets, USP
4mg

DESCRIPTION
Methy]prednisolone is a glucocorticoid. Glucocorticoids are adrenal cortical steroids, both naturally occurring and synthetic, which are readily absorbed from the gastrointestina) tract. Methy]prednisolone occurs as a white, practically white, odorless, crystalline powder. It is sparingly soluble in alcohol, in ether, 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 methy]prednisolone is 11b, 17a, 21-trihydroxy-4-methylprednisolone, and the molecular weight is 374.48. The structural formula is represented below.

\[
\begin{align*}
\text{HO} & \\
\text{CH}_{3} & \\
\text{HO} & \\
\text{CH}_{3} & \\
\text{HO} & \\
\text{CH}_{3} & \\
\end{align*}
\]

Each methylprednisolone tablet for oral administration contains 4 mg methylprednisolone.

CLINICAL PHARMACOLOGY
Naturally occurring glucocorticoids (hydrocortisone or cortisol) are the first choice; synthetic analogs may be used in conjunction with mineralocorticoids where applicable, in the management of adrenocortical insufficiency.

Gluco]corticoids 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 cortisol is the first choice; synthetic analogs may be used in conjunction with mineralocorticoids where applicable, in the management of adrenocortical insufficiency).
Congenital adrenal hyperplasia
Hyperthyroidism 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 bunions
Systemic lupus erythematosus
Acute exacerbations of lupus erythematosus
3. Collagen Diseases
During an exacerbation or as maintenance therapy in selected cases of:
Systemic lupus erythematosus
Systemic dermatomyositis (polyarteritis)
4. Dermatologic Diseases
Bullous dermatitis herpetiformis
Severe pemphigus vulgaris (Stevens-Johnson syndrome)
Severe toxic epidermal necrolysis
Exfoliative dermatitis
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
6. Ophthalmic Diseases
Severe acute and chronic allergic and inflammatory processes involving the eye and its adnexa such as:
Allergic conjunctivitis
Anterior uveitis
Sympathetic ophthalmia
7. Respiratory Diseases
Bronchial asthma
Acute pulmonary edema
8. Miscellaneous Diseases
Idiopathic thrombocytopenia purpura in adult
Secondary thrombocytopenia in adults
Acquired (autoimmune) hemolytic anemia
Congenital (erythropoietic) hypoplastic anemia
9. Neoplastic Disease
For palliative management of:
Leukemia and lymphomas in adults
10. Gastrointestinal Disease
To induce a diuresis or remission of proteinuria in the nephrotic syndrome, without uremia, of the idiopathic type or that due to lesions associated with the myeloma;
11. Adjunctive Therapy
To tide the patient over a critical period of the disease in:
Autoimmune collagen diseases
12. Neurologic System
Acute exacerbations of multiple sclerosis
13. Miscellaneous
Tuberculosis meningitis with subarachnoid block or impending block when used concurrently with appropriate antimicrobial chemotherapy.
Tuberculosis with neurologic or myoccardial involvement.
CONTAMINATION
Some rare infections and known hypersensitivity to components.

WARNINGS
In patients on corticosteroid therapy subjected to unusual stress, increased dosage of rapidly acting corticosteroids below, 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 anterior 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/fetus. Women who have received substantial doses of corticosteroids during pregnancy should be carefully observed for signs of intrauterine hypothyroidism.

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 in high doses, because of possible hazards of neurological complications and a lack of antibody response.

The use of methyprylon tablets in active tuberculosis should be restricted to those cases of mild or minimal disease in which the corticosteroids are used for the management of the disease in conjunction with an appropriate antituberculous regimen. If corticosteroids are indicated in patients with latent tuberculosis or tuberculous meningitis, close observation is necessary as reactivation of the disease may occur.

During prolonged corticosteroid therapy, these patients should receive chemoprophylaxis. Patients who are on immunosuppressant drugs are more susceptible to infections than healthy children. Chickenpox and measles, for example, can have a Children who are on immunosuppressant drugs are more susceptible to infections than healthy children. Chickenpox and measles, for example, can have a particular serious 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 globulin (VZIG) or pooled intravenous immunoglobin (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 reinstated. Since mineralocorticoid secretion may be impaired, salt and potassium supplementation should be administered concurrently. There is an enhanced effect of corticosteroids on patients with hypothyroidism and in those withCushing's syndrome.
Corticosteroids should be used cautiously in patients with ocular herpes simplex because of possible herpetic keratitis. The lowest possible dose of corticosteroids should be used to control the condition under treatment, and when reduction in dosage is possible, the reduction should be gradual. Psychic derangements may occur when corticosteroids are used, ranging from euphoria, insomnia, mood swings, personality changes, and severe depression, to frank psychotic manifestations. Also, existing emotional lability or psychotic tendencies may be exaggerated by corticosteroids.
Aspirin should be used cautiously in conjunction with corticosteroids in hypoprothrombinemia.
Steroids should be used with caution in non-specific ulcerative colitis, if used in a small number of cases, patients may not respond to the treatment.

If steroids are used in a small number of cases, patients may not respond to the treatment.

**ADVERSE REACTIONS**

Fluid retention, potassium loss, hypokalemic alkalosis, anaphylactic reaction, lymphopenia, and increased sensitivity are observed.

**DOSAGE AND ADMINISTRATION**

The initial dosage may be 6 mg to 10 mg of methylprednisolone per day. Larger doses may be required if the symptoms are severe. The dosage may be reduced gradually once the symptoms have subsided.

**INFORMATION FOR THE PATIENT**

Patients who are treated with methylprednisolone should be advised to avoid exposure to known or suspected allergens and to avoid known or suspected allergens. If exposed, patients should seek medical advice.

**ALLERGENS**

Methylprednisolone is a corticosteroid and may cause anaphylactic reactions. Patients should be advised to avoid exposure to known or suspected allergens and to seek medical advice if exposed.

**DOSAGE AND ADMINISTRATION**

The initial dosage may be 6 mg to 10 mg of methylprednisolone per day. Larger doses may be required if the symptoms are severe. The dosage may be reduced gradually once the symptoms have subsided.
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 corticosteroid therapy is anticipated.

3) In severe disease processes in which corticosteroid 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 allergy and collagen diseases. It is important to keep the period of initial suppressive dose as short as possible particularly when subsequent use of alternate day therapy is intended.

Once corticosteroids have been established, two courses are available: (a) change to alternate day therapy and then gradually reduce the amount of corticosteroid given every other day or (b) following control of the disease process reduce the daily dose of corticosteroid to the lowest effective level as rapidly as possible and then change over to an alternate day schedule. Theoretically, course (b) 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 corticosteroids for long periods of time (eg, patients with rheumatoid arthritis). Since these patients may already have a suppressed ACTH 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 institute 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, desoximetasone and betamethasone).

6) The maximal activity of the adrenal cortex is between 7 am and 3 pm, and is minimal between 4 pm and midnight. Exogenous corticosteroids suppress adrenocortical activity the least, when given at the time of maximal activity (pm).

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 corticosteroid dose for control. Once control is again established alternate day therapy may be reinstated.

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 corticosteroid therapy is being considered.

HOW SUPPLIED:
Methylprednisolone tablets, 4 mg are white, oval, quadrangular tablets debossed "42/169/4" on the upper and "4" on the lower.
They are supplied in bottles of 100
NDC #0054-4216-28
500
NDC #0054-4216-35
1000
NDC #0054-4216-38
Unit of use packs NDC #0054-4216-13
Dispense in a tight light-resistant container as defined in the USP.
Store at controlled room temperature 15°-30°C (59°-86°F).
Caution: Federal law prohibits dispensing without prescription.
NDC 0254-4216-28
METHYLPREDNISOLONE TABLETS, USP
4 mg

CAUTION: Federal law prohibits dispensing without prescription.
100 TABLETS

NDC 0254-4216-35
METHYLPREDNISOLONE TABLETS, USP
4 mg

CAUTION: Federal law prohibits dispensing without prescription.
500 TABLETS

NDC 0254-4216-38
METHYLPREDNISOLONE TABLETS, USP
4 mg

CAUTION: Federal law prohibits dispensing without prescription.
1000 TABLETS
METHYL PREDNISOLONE TABLETS USP 4 mg

DOSAGE DIRECTIONS

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 later 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.

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

2nd day
Take 1 tablet before breakfast, 1 tablet after lunch and after 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.

LOT:  
EXP:

MFG by
VINTAGE PHARMACEUTICALS
CHARLOTTE, NC. 28206

TO REMOVE TABLETS, PRESS FROM OTHER SIDE