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 or almost white, odorless, crystalline powder. Its molecular weight is 374.48. The structural formula is represented below:

\[
\text{CH}_2\text{OH} \quad \text{CO} \quad \text{H}, 11 \quad \text{b} \quad \text{and the}
\]

Methylprednisolone Tablets are indicated in the treatment of the symptoms and signs of adrenocortical insufficiency (either primary or secondary) associated with such diseases as Addison’s disease, hypopituitarism, and hyperadrenocorticism due to exogenous adrenocortical steroid administration. Methylprednisolone is used in the treatment of a diverse range of inflammatory and noninflammatory conditions. Therapy should not be undertaken in patients who are on corticosteroids, especially on high doses, because of possible hazards and adverse reactions. When prolonged corticosteroid treatment is necessary, it is advisable to achieve replacement therapy first and then reduce dosage gradually of the corticosteroid to avoid a flare-up of symptoms. During prolonged corticosteroid therapy, these patients should receive chemoprophylaxis.

CLINICAL PHARMACOLOGY

Methylprednisolone is a glucocorticoid with the following properties:

- **Absorption**: Methylprednisolone is readily absorbed from the gastrointestinal tract.
- **Distribution**: It is distributed widely in body tissues and fluids, including cerebrospinal fluid.
- **Metabolism**: It is metabolized in the liver and conjugated with sulfate and glucuronide before excretion in the urine.
- **Excretion**: It is excreted mainly in the urine and to a lesser extent in the feces.

CLINICAL PHARMACOKINETICS

Methylprednisolone is rapidly and completely absorbed from the gastrointestinal tract. Peak plasma levels are achieved within 1-2 hours. It is extensively metabolized in the liver before excretion in the urine. The half-life of methylprednisolone is approximately 2-3 hours.

INDICATIONS AND USAGE

Methylprednisolone Tablets are indicated in the following conditions:

- **Adrenocortical Insufficiency**: Primarily in patients with adrenocortical insufficiency as determined by the increment test or other methods. In adrenocortical insufficiency of any etiology, methylprednisolone is used to replace the corticosteroids that the body cannot produce.
- **Autoimmune Disorders**: Used in the treatment of autoimmune disorders such as systemic lupus erythematosus, rheumatoid arthritis, and polymyositis.
- **Infections**: Used for the suppression of immune reactions in infections or postoperative states.

CONTRAINdications

Methylprednisolone Tablets are contraindicated in the following conditions:

- **Known hypersensitivity**: To methylprednisolone or any of its components.
- **Severe hepatic disease**: Use of methylprednisolone in patients with severe hepatic disease is associated with an increased risk of adverse reactions.

PRECAUTIONS

General Precautions

Drug-induced secondary adrenocortical insufficiency may be minimized by gradual reduction of dosage in patients on prolonged corticosteroid therapy. When a decision has been made to discontinue therapy, replacement therapy should be instituted.

Drug interactions:

Methylprednisolone may alter the response to anticoagulants and to drugs that interact with calcium metabolism. Methylprednisolone may also increase the sensitivity of the myocardium to digitalis glycosides.

Overdosage:

In cases of overdosage, symptoms such as restlessness, irritability, insomnia, and sometimes signs of infection, are observed. These signs may be controlled by reduction of dosage or discontinuation of therapy, and symptomatic treatment. In the event of overdosage, supportive and symptomatic measures should be employed.

Hypersensitivity reactions:

Methylprednisolone Tablets may cause hypersensitivity reactions such as skin rash or bronchospasm. Patients with a history of atopy or a history of hypersensitivity to other corticosteroids may be more likely to experience such reactions.

Hyperglycemia and diabetes mellitus:

Patients on long-term corticosteroid therapy may develop glucose intolerance or frank diabetes mellitus. Close monitoring of blood glucose is recommended in such patients, especially during initiation or withdrawal of corticosteroid therapy.

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

- 4 mg
- 8 mg
- 16 mg
- 32 mg
- 48 mg
- 80 mg

Dosage and Administration

The initial dosage of Methyprednisolone Tablets may be from 4 mg to 48 mg of methyprednisolone per day depending on the specific disease process and the degree of severity. The physician should consider the following when determining the proper dosage of Methyprednisolone Tablets:

1. The condition being treated.
2. The severity of the condition.
3. The age, weight, and condition of the patient.
4. The response of the condition to therapy.
5. The method of administration (oral, intramuscular, or intravenous).

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.

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

1. The initial dosage of alternate day therapy is not the same as the usual daily dosage. The benefit of ADT should not encourage the discontinuance of the concomitant therapy, and the incidence of adrenal suppression may be higher than in patients on continuous daily therapy.

2. ADT may be desirable for patients with chronic ulcers of the intestinal tract who require high-dose corticosteroid therapy in order to obtain control. The benefits of ADT may not outweigh the disadvantages,

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ACTH = Adrenocorticotropic hormone

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