DESCRIPTION
Methylprednisolone sodium succinate is a corticosteroid, both naturally occurring and synthetic, which are readily absorbed from the gastrointestinal tract. Methylprednisolone sodium succinate is a sterile white, odorless, crystalline powder. It is sparingly soluble in alcohol, in dioxane, and in methanol, slightly soluble in acetone, and very slowly soluble in ether. It is practically insoluble in water.

The chemical name for Methylprednisolone sodium succinate is pregna-1,4-diene-3,20-dione, 11, 17, 21-trihydroxy-6-methyl- (6α, 11β) and the molecular weight is 374.46. The structural formula is represented below:

![Chemical Structure of Methylprednisolone Sodium Succinate]


table

Included are the following:\n
- Systemic lupus erythematosus\n- Systemic dermatomyositis (polymyositis)\n- Acute rheumatic fever\n- Dermatologic diseases\n- Bullous dermatitis herpetiformis\n- Severe erythema multiforme (Stevens-Johnson syndrome)\n- Severe seborrheic dermatitis\n- Exfoliative dermatitis\n- Myositis\n- Myositis associated with systemic lupus erythematosus

5. Allergic States\n
- Contact dermatitis or incapacitating allergic conditions\n- Intractable to adequate trials of conventional treatment
- Severe or perennial allergic rhinitis
- Drug hypersensitivity reactions
- Serum sickness
- Bronchial asthma
- Contact dermatitis

6. Ophthalmic Diseases\n
- Severe acute and chronic allergic and inflammatory processes involving the eye and its adnexa such as: allergic conjunctivitis, keratitis, iritis, episcleritis, and scleritis

INDICATIONS
Methylprednisolone sodium succinate is indicated for the management of the disease in conjunction with an appropriate antibacterial regimen.

The use of Methylprednisolone sodium succinate 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 antibacterial regimen.

If corticosteroids are indicated in patients with latent tuberculosis or tuberculosis reactivity, close observation is necessary as reactivation of the disease may occur.

PRECAUTIONS
- General Precautions
- Methylprednisolone sodium succinate is a potent anti-inflammatory agent and should be used with caution in patients who have had a history of peptic ulcer disease. It may predispose to or aggravate peptic ulceration or exacerbate existing ulcerative conditions.

- Patients with a history of peptic ulcer disease should be monitored closely for signs of ulceration or perforation.

- Methylprednisolone sodium succinate should be used with caution in patients with a history of hypersensitivity reactions, including bronchial asthma, in susceptible individuals.

- The overall incidence of FDC & Yellow No. 5 (tartrazine) sensitivity in the general population is very rare; however, it is frequently seen in patients who also have aspirin hypersensitivity.

- Convulsions have been reported with concurrent use of methylprednisolone and cyclosporin. 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

Patients 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 globulin (VZIG) or pooled intravenous immunoglobulin (IVIG), as appropriate, may be indicated. If chickenpox develops, treatment with antiviral agents may be considered.

ACTIONs
Naturally occurring glucocorticoids (hydrocortisone and cortisone), which also have salt-retaining properties, are used as replacement therapy in adrenocortical insufficiency 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 modulate the body's immune responses to diverse stimuli.

INDICATIONS
Methylprednisolone sodium succinate is indicated for the following conditions:

1. Endocrine Disorders\n   - Primary or secondary adrenal 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
   - Non-suppressive thyroiditis
   - Hypercalcaemia associated with cancer
   - Rheumatoid 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 long-term maintenance therapy)
   - Ankylosing spondylitis
   - Acute and subacute bursitis
   - Synovitis of osteoarthritis
   - Acute nonspecific tenosynovitis
   - Post-traumatic osteoarthritis

3. Collagen Diseases

- Systemic lupus erythematosus
- Systemic dermatomyositis (polymyositis)
- Acute rheumatic fever
- Dermatologic Diseases
- Bullous dermatitis herpetiformis
- Severe erythema multiforme (Stevens-Johnson syndrome)
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Each Methylprednisolone sodium succinate tablet contains 2 mg, 4 mg, 8 mg, 16 mg, 24 mg or 32 mg of methylprednisolone.

APPROVED
DECEMBER 28, 1993

Medrol®
brand of methylprednisolone tablets
Upjohn
810 487 613a

Medrol®
brand of methylprednisolone tablets

During prolonged corticosteroid therapy, these patients should receive chemophrophylaxis.

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 globulin (VZIG) or pooled intravenous immunoglobulin (IVIG), as appropriate, may be indicated. If chickenpox develops, treatment with antiviral agents may be considered.

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**Medrol**

**brand** of methylprednisolone tablets

**ADVERSE REACTIONS**

Fluid retention  
Potassium loss  
Hypokalemia

Steroid myopathy  
Osteoporosis

Intravascular compression fractures  
Aspheric necrosis of femoral and humeral heads

Pathologic fracture of long bones  
Gastrointestinal

Pepic ulcer with possible perforation and hemorrhage  
Abdominal distension

Ulcerative esophagitis

Dermatologic

Impaired wound healing

Petaeiae and ecchymoses  
Facial erythema

May suppress reactions to skin tests

Neurological

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

Convulsions

Vertigo

**Endocrine**

Decreased carbohydrate tolerance

Manifestations of latent diabetes mellitus

Increased requirements of insulin or oral hypoglycemic agents in diabetics

**Ophthalmic**

Posterior subcapsular cataracts  
Intracocular pressure increase

Glaucoma

Exophthalmos

**Metabolic**

Negative nitrogen balance due to protein catabolism

The following additional reactions have been reported:

- **Urticaria** and other allergic, anaphylactic or hypersensitivity reactions.

**DOSEAGE AND ADMINISTRATION**

The initial dosage of MEDROL 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 obtained. If after a reasonable period of time there is a lack of satisfactory clinical response, MEDROL 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 dosage maintenance 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 MEDROL 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.

**Medrol**

**brand** of methylprednisolone tablets

**Multiple Sclerosis:** In treatment of acute exacerbation, corticosteroid doses of methylprednisolone for a week followed by 80 mg every other day for 1 month may be used. The total daily dose of methylprednisolone is equivalent to 5 mg of prednisone.

**Mycosis of the Tongue:** After the initial doses have been reduced to a minimal level, further doses should be given for periods of 4 days, then 2 days, then 1 day, then continued with alternate day therapy.

**The following control of administration of the disease process:** The initial daily dose of corticosteroid should be continued until satisfactory clinical response is obtained, usually for 4 to 5 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 corticosteroid given every other day or (b) following control of the disease process reduce the daily dose of prednisone to the lowest effective level as rapidly as possible and then change over to an alternate day therapy. Theoretically, course (a) may be preferable.

**Because of the advantages of ADT, it may be desirable to try patients on this form of therapy who have been on long-term courses of methylprednisolone for many years.** This type of treatment may be particularly useful in patients who 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.

**If the patient deteriorates above a certain corticosteroid, because of their prolonged suppressive effect on adrenal activity, are not recommended for alternate day therapy (eg, dexamethasone and betamethasone).**

**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 adrenal cortical activity the least, when given at the time of maximal activity (am). 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 necessarily be obtainable in all patients. An explanation of the benefits of ADT will help the patient to understand and tolerate the possible flare-ups in symptoms which may occur in the latter part of the off-stereoid day. Other symptomatic therapy may be added or increased at this time if needed.

**In the event of an acute flare-up of the disease process, it may be necessary to return to a full suppressive daily corticosteroid dose for control. Once control is established alternate day therapy may be reinitiated.**

**Although many of the undesirable features of corticosteroid therapy can be minimized by ADT, in any therapeutic situation, the physician must carefully weigh the benefits ratio of continued therapy in the patient in whom corticosteroid therapy is being considered.**

**HOW SUPPLIED**

**Medrol** Tablets, effipecial and scored, are available in the following strengths and package sizes:

- 2 mg (pink) Bottles of 100 NDC 0009-0049-02
- 4 mg (pink) Bottles of 100 NDC 0009-0056-01
- 8 mg (peach) Bottles of 100 NDC 0009-0022-01
- 16 mg (white) Bottles of 100 NDC 0009-0073-01
- 24 mg (yellow) Bottles of 25 NDC 0009-0155-01
- 32 mg (peach) Bottles of 25 NDC 0009-0176-01

Store in controlled room temperature 15° to 30° C (59° to 86° F).

Caution: Federal law prohibits dispensing without prescription.

The Upjohn Company
Kalazoo, Michigan 49001, USA

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