Your doctor is the best resource for medical advice and information. The health information contained herein is provided for educational / awareness purposes only and is not intended to replace discussions with a medical practitioner and/or medical advice or be construed as a promotional information.

Package Leaflet: Information for the user
Methylprednisolone Tablets I.P.
4 mg, 8 mg and 16 mg Tablets
MEDROL®

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- If you have any further questions, ask your doctor.
- This medicine has been prescribed for you only. Do not pass it on to other people. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Medrol (Methylprednisolone) is and what it is used for

Methylprednisolone is a corticosteroid used for its anti-inflammatory effect in:

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).

1. Congenital adrenal hyperplasia;
2. Non-suppurative thyroiditis;
3. Hypercalcemia associated with cancer.

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Non-endocrine Disorders

1. Rheumatic Disorders

As adjunctive therapy for short-term administration (to tide the patient over an acute episode or exacerbation) in:

• psoriatic arthritis	• acute gouty arthritis
• rheumatoid arthritis, including juvenile rheumatoid arthritis (selected cases may require low-dose maintenance therapy)	• post-traumatic osteoarthritis
• ankylosing spondylitis	• synovitis of osteoarthritis
• acute and subacute bursitis	• epicondylitis
• acute non-specific tenosynovitis	

2. Collagen Diseases

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

• systemic lupus erythematosus	
• systemic dermatomyositis (polymyositis)	
• acute rheumatic carditis	

3. Dermatologic Diseases

• pemphigus	• mycosis fungoides
• bullous dermatitis herpetiformis	• severe psoriasis
• severe erythema multiforme (Stevens-Johnson syndrome)	• severe seborrheic dermatitis
• exfoliative dermatitis	

4. 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
• angioneurotic edema	• urticaria

5. Ophthalmic Diseases

Severe acute and chronic allergic and inflammatory processes involving the eye and its adenexa such as:

• allergic corneal marginal ulcers	• allergic conjunctivitis
• herpes zoster ophthalmicus	• keratitis
• anterior segment inflammation	• chorioretinitis
• diffuse posterior uveitis and choroiditis	• optic neuritis
• sympathetic ophthalmia	• iritis and iridocyclitis

6. Respiratory Diseases

• symptomatic sarcoidosis	• fulminating or disseminated pulmonary tuberculosis when used concurrently with appropriate antituberculous chemotherapy
• Leoffler's syndrome not manageable by other means	• aspiration pneumonitis
• berylliosis	

7. Hematologic Disorders

• idiopathic thrombocytopenic purpura in adults	• erythroblastopenia (RBC anemia)
• secondary thrombocytopenia in adults	• congenital (erythroid) hypoplastic anemia
• acquired (autoimmune) hemolytic anemia	

8. Neoplastic Diseases

For palliative management of:

- Leukemias and lymphomas in adults;
- Acute leukemia of childhood.

9. Edematous States

- To induce a diuresis or remission of proteinuria in the nephrotic syndrome, without uremia, or the idiopathic type or that due to lupus erythematosus.

10. Gastrointestinal Diseases

To tide the patient over a critical period of the disease in:

- Ulcerative colitis;
- Regional enteritis.

11. Nervous System

- Acute exacerbation of multiple sclerosis;
- Management of edema associated with brain tumor.

12. Organ Transplantation

13. Miscellaneous

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

- Trichinosis with neurologic or myocardial involvement.

2. What you need to know before you take Medrol (Methylprednisolone)

Do not take Medrol (Methylprednisolone)

- If you are allergic (hypersensitive) to the active substances or to any of the other ingredients in this medicine (listed in section 6).
- If you have systemic fungal infections.

Administration of live or live, attenuated vaccines is contraindicated in patients receiving immunosuppressive doses of corticosteroids.

Warnings and precautions

- Corticosteroids may mask some signs of infection, and new infections may appear during their use. Infections with any pathogen including viral, bacterial, fungal, protozoan or helminthic infections, in any location of the body, may be associated with the use of corticosteroids alone or in combination with other immunosuppressive agents.
- During treatment with corticosteroids, patients should not be vaccinated against smallpox.
- Corticosteroids, including methylprednisolone, can increase blood glucose, worsen pre-existing diabetes, and predispose those on long-term corticosteroid therapy to diabetes mellitus.
- Inform the doctor before taking the medication, if you have a preexisting Seizure disorder, heart failure or hypertension, inflammation or ulcers in your gut.
- 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.
- There is an enhanced effect of corticosteroids if you are suffering from hypothyroidism and has cirrhosis.
- 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 increased by corticosteroids.

- In post marketing experience tumor lysis syndrome (TLS) has been reported in patients. Patients at high risk of TLS, should be monitored closely and appropriate precautions should be taken.

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.

Other medicines and Medrol (Methylprednisolone):

Talk to your doctor before taking Medrol (Methylprednisolone), if you are taking or planning to take any of the following medications:

- Medications used in Myasthenia Gravis
- Antidiabetics
- Medications used to treat vomiting (Aprepitant, Fosaprepitant)

- Antifungals (Ketoconazole and Itraconazole) and Anti virals
- Calcium channel blockers (Diltiazem)
- Contraceptives (Ethinylestradiol/Norethidrone)
- Immunosuppresants (Cyclosporine, Cyclophosphamide, Tacrolimus)
- Macrolide anibacterials (Clarithromycin, Erythromycin, Troleandomycin)
- NSAIDs (high-dose Aspirin)
- Potassium lowering agents (Amphotericin B, Xanthines, Beta2 agonists)

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before receiving this medicine.

Driving and using machines

The effect of corticosteroids on the ability to drive or use machinery has not been systematically evaluated. Undesirable effects, such as dizziness, vertigo, visual disturbances and fatigue are possible after treatment with corticosteroids. If you experience any of these symptoms, you should not drive or operate machinery.

3. How to take Medrol (Methylprednisolone)

Always take this medicine exactly as your doctor has told you. Check with your doctor if you are not sure. The dose will be determined based on the severity of the disease and your response to the therapy.

It is very important to regularly monitor the treatment and not change it or stop abruptly without your doctor's advice.

In case of long-term treatment, do not abruptly stop treatment but follow your doctor's recommendations on reducing doses.

If you take more Medrol (Methylprednisolone) than you should

Consult your doctor immediately.

If you forget to take Medrol (Methylprednisolone)

To be effective, this medicine should be used regularly. However, if you forget to take a dose, continue the treatment normally.

Do not take a double dose to make up for the dose that you missed.

If you stop taking Medrol (Methylprednisolone)

Do not abruptly stop taking the tablets. Consult your doctor before you stop taking the medication.

If you have any further questions on the use of this medicine, ask your doctor.

4. Possible side effects

Like all medicines, Medrol (Methylprednisolone) can cause side effects, although not everybody gets them.

Infections and infestations: Infection, opportunistic infections, inflammation of the thin lining (peritoneum) around the gut and stomach (peritonitis)

Blood and lymphatic system disorders: Increase in white blood cells (leukocytosis)

Immune system disorders: Drug hypersensitivity such as allergic reaction (rash, itching etc.).

Endocrine disorders: Changes in body appearance (Cushingoid appearance), Hypopituitarism, Steroid withdrawal syndrome.

Interference with the pituitary-adrenal axis function, particularly in times of stress. Alteration of growth in the children.

Metabolism and nutrition disorders: Metabolic acidosis, sodium retention, fluid retention, alkalosis hypokalaemic, dyslipidaemia, impaired glucose tolerance, increased insulin requirement (or oral hypoglycemic agents in diabetics), lipomatosis, increased appetite (which may result in weight gain).

Psychiatric disorders: Affective disorder (including low mood, euphoria, affect lability, drug dependence, suicidal ideation), psychotic disorders (including mania, delusion, hallucination, and schizophrenia, psychotic behavior, mental disorder, personality change, confusional state, anxiety, mood swings, abnormal behavior, sleeplessness).

Nervous system disorders: Epidural lipomatosis, increased intracranial pressure (with papilloedema [Benign intracranial hypertension]), fits, amnesia, cognitive disorder, dizziness, headache.

Eye disorders: Cataract subcapsular, exophthalmos, high pressure in the eye (glaucoma), chorioretinopathy, blurred vision

Ear and labyrinth disorders: Feeling of spinning, dizziness (vertigo).

Cardiac disorders: Alterations in electrolyte balance, which in rare cases may lead to increased blood pressure and heart failure.

Vascular disorders: Thrombotic events, high blood pressure, low blood pressure, warmth and reddening of the skin (Flushing)

Respiratory, thoracic and mediastinal disorders: Blood clot in the lungs which causes chest pain and breathlessness (pulmonary embolism), hiccups.

Gastrointestinal disorders: Peptic ulcer (with possible peptic ulcer perforation and peptic ulcer haemorrhage) intestinal perforation, gastric bleeding, Inflammation of the pancreas which causes severe pain in the abdomen and back (pancreatitis), ulcerative oesophagitis, oesophagitis, abdominal distension, abdominal pain, diarrhoea, indigestion.

Skin and subcutaneous tissue disorders: Serious allergic reaction which causes swelling of the face or the throat (angioedema), hirsutism, petechiae, ecchymosis, skin atrophy, redness, excessive sweating, stretch marks, rash, itching, urticaria, acne.

Musculoskeletal and connective tissue disorders: Muscular weakness, myalgia, myopathy, muscle atrophy, osteoporosis, osteonecrosis, pathological fracture, neuropathic arthropathy, arthralgia, delayed growth.

Reproductive system and breast disorders: Menstruation irregular.

General disorders and administration site conditions: Impaired healing, swelling of the ankles, feet, and fingers, fatigue, feeling generally unwell.

Hepatobiliary disorders: Increased liver enzymes (increased alanine aminotransferase, increased aspartate aminotransferase).

Investigations: Increased intraocular pressure, decreased carbohydrate tolerance, decreased blood potassium, increased urine calcium, increased blood alkaline phosphatase, increased blood urea, suppression of reactions to skin tests.

*Injury, poisoning, and procedural complication*s: Spinal compression fracture, tendon rupture (particularly of the achilles tendon).

5. How to store Medrol (Methylprednisolone)

Store below 30°C. Protect from moisture.

6. Contents of the pack and other information

What Medrol (Methylprednisolone) contains

Each uncoated tablet contains 4 mg, 8 mg or 16 mg of Methylprednisolone I.P.

List of Excipients

Medrol 4 mg: Lactose monohydrate, sucrose, calcium stearate, corn starch.

Medrol 8 mg: Lactose monohydrate, sucrose, calcium stearate, corn starch.

Medrol 16 mg: Lactose monohydrate, sucrose, liquid paraffin, calcium stearate, corn starch.

What Medrol (Methylprednisolone) looks like and contents of the pack

Methylprednisolone 4 mg tablets are half oval, elliptical, white tablets, debossed with "MEDROL 4" on one side and double scored on the other.

Methylprednisolone 8 mg tablets are elliptical, convex, white tablets, debossed with "MEDROL 8" on one side and scored on the other.

Methylprednisolone 16 mg tablets are elliptic, convex, white tablets engraved with "MEDROL 16" on one side and a cross score on the other.

Medrol **4 mg**: 10 tablets packed in PVC blister made up of PVC-aluminium/clear PVC foil.

Medrol **8 mg**: 14 tablets packed in PVC blister made up of PVC-aluminium/clear PVC foil.

Medrol **16 mg**: 14 tablets packed in PVC blister made up of PVC-aluminium/PVC foil.

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