

PART III: CONSUMER INFORMATION

PrMEDROL*
(methylprednisolone tablets USP)
4 mg and 16 mg Tablets

This leaflet is part III of a three-part "Product Monograph" published when MEDROL was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about MEDROL. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is used for:

MEDROL is used in the treatment of various conditions such as allergy or inflammation; it can also be used to replace corticosteroid hormone when the body does not produce enough due to problems with the adrenal glands (e.g. adrenal insufficiency)

What it does:

MEDROL contains a corticosteroid hormone. It decreases the body's immune response to certain diseases and reduces symptoms such as swelling and redness.

When it should not be used:

Do not take MEDROL if you have:

- allergies to methylprednisolone or any other steroid medicine or any of the ingredients in MEDROL tablets; or
- any fungal infection.
- viral diseases including vaccinia (cowpox), varicella (chicken pox), and herpes simplex of the eye.

Patients taking MEDROL should not receive live vaccines.

What the medicinal ingredient is:

Methylprednisolone

What the nonmedicinal ingredients are:

Calcium stearate, cornstarch, lactose, mineral oil and sucrose. In addition, the 4 mg tablet contains sorbic acid.

What dosage forms it comes in:

Each elliptical, cross-scored tablet contains: methylprednisolone 4 mg (white, engraved "Medrol 4") or 16 mg (white, engraved "Medrol 16").

WARNINGS AND PRECAUTIONS

Before taking MEDROL, talk to your doctor if you have:

- an infection (such as herpes simplex, chicken pox, tuberculosis, threadworm);
- recently had myocardial infarction (heart attack)
- thromboembolic disorders (bleeding or blood clotting problems)
- brittle bone (osteoporosis);

- high blood pressure
- water retention (oedema);
- heart problems such as heart failure;
- kidney disease;
- diabetes;
- seizures (fits) or other neurological problems;
- thyroid problems;
- muscle pain or weakness (such as myasthenia gravis);
- skin cancer (Kaposi's sarcoma), or a tumor of the adrenal glands (Pheochromocytoma);
- certain eye disease such as glaucoma, cataracts; herpes infection or any problems with the retina;
- liver disease such as cirrhosis;
- certain mental or mood conditions (such as depression)
- stomach or gut problems (ulcer, ulcerative colitis);
- low potassium or calcium;
- weak immune response;
- Cushing's disease (caused by an excess of cortisol hormone);
- high blood sugar;
- had any prior use of MEDROL;
- a condition known as systemic sclerosis, in which your body makes too much of a protein called collagen.

Before you have any operation, tell your doctor, dentist or anesthetist that you are taking MEDROL.

Pregnancy and breast feeding

You must tell your doctor if you are pregnant, think you might be pregnant or are trying to become pregnant as this medicine could slow the baby's growth.

You should tell your doctor if you are breast feeding as small amounts of corticosteroid medicines may get into breast milk.

Children:

Corticosteroids can affect growth in children.

INTERACTIONS WITH THIS MEDICATION

Before taking MEDROL talk to your doctor about all your other medications, including those you bought without prescription, herbal or natural products. Especially if you are taking the following:

- drugs to treat glaucoma and epilepsy such as acetazolamide
- drugs to prevent or alleviate nausea and vomiting such as aprepitant or fosaprepitant
- drugs to treat cancer such as aminoglutethimide or cyclophosphamide
- drugs to "thin" the blood: Anticoagulants such as acenoumarol, phenindione and warfarin
- drugs to treat myasthenia gravis (a muscle condition) such as distigmine and neostigmine
- antibiotics and antifungals (such as ketoconazole, itraconazole, amphotericin B, erythromycin, clarithromycin, troleandomycin, rifampicin and rifabutin)

- aspirin and non-steroidal anti-inflammatory medicines (also called NSAIDs) such as ibuprofen
- drugs to treat epilepsy such as barbiturates, carbamazepine, phenytoin and primidone
- drugs for heartburn and acid indigestion such as cimetidine
- Cyclosporine
- drugs for heart problems or high blood pressure as digoxin and diltiazem
- water pills (Diuretics)
- hormone replacement therapy or hormonal oral contraceptive
- drugs to treat HIV infections such as indinavir or ritonavir
- pancuronium or vecuronium – or other medicines called neuromuscular blocking agents which are used in some surgical procedures
- tacrolimus – used following an organ transplant to prevent rejection of the organ
- vaccines – tell your doctor or nurse if you have recently had, or are about to have any vaccination
- drugs to treat diabetes
- drugs to treat tuberculosis
- drugs to treat high cholesterol (cholestyramine)

Driving and Using Machines

MEDROL may cause dizziness, vertigo, vision problems and fatigue. If you experience these side effects you should not drive or operate machinery.

PROPER USE OF THIS MEDICATION

Usual dose: Between 4 mg to 48 mg daily, depending on your condition and how severe it is.

Your doctor may tell you to take your daily dose as a single dose or in divided doses.

Swallow the tablets with a drink of water. Do not eat grapefruit or drink grapefruit juice while taking MEDROL.

When your condition has improved, your dose will be reduced gradually.

MEDROL should not be stopped abruptly. Do not stop taking MEDROL without talking to your doctor.

Overdose:

In case of drug overdose, contact a health care practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

Missed Dose:

Take the missed dose as soon as you remember it. However, if it is almost time for the next dose, skip the missed dose and continue your regular dosing schedule. Do not take a double dose to make up for a missed one.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Like all medicines, MEDROL can have side effects although not everybody gets them

MEDROL may hide symptoms of infections, may cause latent infections to become active, and may induce infections by normally inoffensive organisms due to lowered body resistance.

Potential side effects of MEDROL include:

Allergic Reactions:

- anaphylaxis (a severe, life-threatening allergic reaction)
- cardiac arrest
- bronchospasm (narrowing of the airway)

Cardiovascular:

- heart failure
- heart attack
- arrhythmia (irregular heartbeat)
- high and low blood pressure
- blood clots
- thrombophlebitis (vein inflammation)
- thrombosis (blood clot within a blood vessel)

Dermatologic:

- thin fragile skin
- impaired wound healing
- swelling
- ecchymosis (spots caused by ruptured blood vessels)
- petechiae (reddish spot containing blood that appears in skin)
- stretch marks
- dry, scaly skin
- rash
- redness
- itching
- acne
- increased sweating
- lightening or darkening of an area of skin
- abscess
- suppressed reactions to skin tests
- thinning hair

Endocrine and Metabolism:

- development of Cushingoid state (abnormal bodily condition caused by excess corticosteroids)
- moon face (enlargement of chin and forehead)
- weight gain
- abnormal fat deposits
- suppression of pituitary-adrenal axis (a condition that could lead to disabling the body's responses to physiological stress such as severe infections or trauma)
- suppression of growth in children
- abnormal hair growth
- new symptoms of diabetes

Gastrointestinal:

- stomach ulcer
- stomach bleeding

- inflammation of the pancreas and esophagus
- perforation of the bowel
- nausea
- vomiting or altered sense of taste (with rapid administration of large doses)
- abdominal pain
- bloating
- diarrhea
- indigestion
- bowel/bladder dysfunction
- increased appetite
- peritonitis

Hepatic:

- enlarged liver

Musculoskeletal:

- loss of muscle mass
- muscle weakness
- muscle pain
- malaise (feeling of general discomfort or uneasiness)
- osteoporosis
- pathological fractures
- vertebral compression fractures
- tendon rupture, (particularly of the Achilles tendon)
- Charcot joint disease (neuropathic arthropathy)
- joint pain

Neurologic:

- seizures
- headache
- dizziness
- amnesia
- vertigo
- pain and tenderness
- impaired sensation, strength, and reflexes
- sensation of tingling, tickling, prickling, or burning of a person's skin

Ophthalmologic:

- cataracts
- increased intraocular pressure
- glaucoma

Psychiatric:

- anxiety
- confusion
- depression
- hallucination
- emotional instability
- euphoria (intense feelings of well-being, elation, happiness, excitement and joy)
- insomnia
- mood swings
- personality changes
- suicidal ideation

Sexual Function/Reproduction:

- menstrual irregularities
- increased or decreased motility and number of sperm

Hematology:

- Above normal white blood cell count
- Above normal cholesterol or triglycerides
- Abnormal blood tests (ex. liver enzymes and urea)

Other:

- fatigue, hiccups, swelling

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

| Symptom / effect | Talk with your doctor or pharmacist | | Seek IMMEDIATE medical attention |
|---|-------------------------------------|--------------|----------------------------------|
| | Only if severe | In all cases | |
| Burst or bleeding ulcers: symptoms of which are stomach pain, bleeding from the back passage, black or bloodstained stools and/or vomiting blood | | | √ |
| Flare up of a previous TB : symptoms of which could be coughing blood or pain in the chest | | | √ |
| Infection: symptoms might include a raised temperature and feeling unwell. | | √ | |
| High blood pressure (symptoms of which are headaches or generally feeling unwell) | | √ | |
| Swelling | | √ | |
| Cramps and spasms | | √ | |
| Vision changes | | √ | |
| Feeling depressed, including thinking about suicide | | √ | |
| Feeling high (mania) or moods that go up and down | | √ | |
| Feeling anxious, having problems sleeping, difficulty in thinking or being confused and losing your memory | | √ | |
| Mental/mood changes (such as mood swings, depression, suicidal thinking, agitation, anxiety) | | √ | |
| Feeling, seeing or hearing things which do not exist. | | √ | |
| Increased thirst/urination | | √ | |

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

| Symptom / effect | Talk with your doctor or pharmacist | | Seek IMMEDIATE medical attention |
|--|-------------------------------------|--------------|----------------------------------|
| | Only if severe | In all cases | |
| Fast/pounding/ irregular heartbeat | | √ | |
| Acne | √ | | |
| Poor wound healing | √ | | |
| Thinning of skin | √ | | |
| Increased hair growth | √ | | |
| Dizziness, fatigue, weakness, shortness of breath (congestive heart failure) | | | √ |
| Muscle weakness | | | √ |
| Bone/joint pain | | | √ |
| Prone to bone fracture or breaking | | | √ |

This is not a complete list of side effects. For any unexpected effects while taking MEDROL, contact your doctor or pharmacist.

HOW TO STORE IT

Store between 15°C and 30°C in the original package. Do not take MEDROL after the expiry date shown on the package. Keep out of reach and sight of children.

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- Report online at www.healthcanada.gc.ca/medeffect
- Call toll-free at 1-866-234-2345
- Complete a Canada Vigilance Reporting Form and:
 - Fax toll-free to 1-866-678-6789, or
 - Mail to: Canada Vigilance Program
Health Canada
Postal Locator 0701E
Ottawa, Ontario
K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at www.healthcanada.gc.ca/medeffect.

NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

This document plus the full Product Monograph, prepared for health professionals can be found at: <http://www.pfizer.ca> or by contacting the sponsor, Pfizer Canada Inc., at: 1-800-463-6001.

This leaflet was prepared by Pfizer Canada Inc.

Last revised: May 8, 2018