

## **PATIENT MEDICATION INFORMATION**

### **READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE**

**PrMEDROL\***

#### **Methylprednisolone tablets USP**

Read this carefully before you start taking **MEDROL** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **MEDROL**.

#### **What is MEDROL used for?**

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

#### **How does MEDROL work?**

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

#### **What are the ingredients in MEDROL?**

Medicinal ingredients: Methylprednisolone

Non-medicinal ingredients: Calcium stearate, cornstarch, lactose, mineral oil and sucrose. In addition, the 4 mg tablet contains sorbic acid.

#### **MEDROL comes in the following dosage forms:**

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

#### **Do not use MEDROL if:**

- you have allergies to methylprednisolone or any other steroid medicine or any of the ingredients in MEDROL tablets; or
- you have any fungal infection or any untreated infection.
- you have viral diseases including vaccinia (cowpox), varicella (chicken pox), and herpes simplex of the eye.
- you have recently received a type of vaccine called a live or live / attenuated vaccine. Do not receive this vaccine during treatment with MEDROL.

**To help avoid side effects and ensure proper use, talk to your healthcare professional before you take MEDROL. Talk about any health conditions or problems you may have, including if you:**

- have a known or suspected allergy to cow's milk or its components or other dairy products.
- have an infection (such as herpes simplex, chicken pox, tuberculosis, threadworm); **If you or your child is exposed to measles or chickenpox during treatment with MEDROL, contact your**

**healthcare professional immediately. Serious or fatal side effects can occur if you or your child have not already had these infections.**

- have recently had or are about to have any vaccine
- have recently had heart problems such as a heart attack (myocardial infarction), heart failure or heart disease
- have bleeding or blood clotting problems (thromboembolic disorders)
- have brittle bone (osteoporosis);
- have high blood pressure
- have water retention (oedema);
- have kidney disease;
- have diabetes or high blood sugar;
- have seizures (fits) or other nervous system problems;
- have thyroid problems;
- have muscle pain or weakness (such as myasthenia gravis);
- have skin cancer (Kaposi's sarcoma), or a tumor of the adrenal glands (pheochromocytoma);
- have certain eye disease such as glaucoma, cataracts; herpes infection or any problems with the retina;
- have liver disease such as cirrhosis;
- have certain mental or mood conditions (such as depression)
- have stomach or gut problems (such as ulcers or ulcerative colitis);
- have low potassium or calcium;
- have weak immune response; Tell your healthcare professional if you suspect an infection has occurred, as corticosteroids can make infections more likely and may mask their signs.
- have Cushing's disease (a condition caused by having an excess of cortisol hormone);
- have had any prior use of MEDROL;
- have a condition known as systemic sclerosis. This is a condition in which your body makes too much of a protein called collagen.

**Other warnings you should know about:**

**Serious Side Effects:** MEDROL can cause serious side effects, including:

- skin cancer (Kaposi's sarcoma): Kaposi's sarcoma has been reported with corticosteroid therapy, such as MEDROL. Stopping treatment of MEDROL may result in signs of this cancer going away.
- tumor of the adrenal glands (pheochromocytoma). This tumor has been reported with corticosteroid therapy, such as MEDROL. Pheochromocytoma may cause death.
- fat deposition on or outside the lining of the spine (epidural lipomatosis). Taking corticosteroids in high doses for a long period of time can cause epidural lipomatosis.

**Surgery**

**Before you have any operation,** tell your healthcare professional (for example your doctor, dentist or anesthetist) that you are taking MEDROL.

**Pregnancy and breastfeeding:**

- If you are pregnant, or still able to get pregnant and/or breast-feed, there are specific risks you must discuss with your healthcare professional. Taking MEDROL may:
  - slow the growth and cause low birth weight of the baby.

- cause cataracts in babies. This risk is associated with mothers who take corticosteroids for a long period of time during pregnancy.
- If you are breastfeeding or planning to breastfeed, tell your healthcare professional.
- You should tell your healthcare professional if you are breast feeding as small amounts of corticosteroid medicines may get into breast milk.

**Male fertility:**

Taking MEDROL may affect male fertility.

**Stopping treatment:**

If you suddenly stop taking MEDROL, you may experience:

- Serious adrenal insufficiency. This is when the body does not make enough of the cortisol hormone. This may cause death.
- “Withdrawal syndrome”. This includes symptoms such as anorexia, nausea, vomiting, lack of energy, headache, fever, joint pain, peeling of skin, muscle pain, weight loss, and/or low blood pressure.

**Skin:**

- Tell your healthcare professional you are taking MEDROL since it can affect the results of skin tests.

**Children (less than 18 years of age):**

- Children may have their growth slowed with use of MEDROL.
- Your healthcare professional will give the child the lowest dose to reduce the risk of slowing growth.
- Your healthcare professional will carry out tests on the child if they are taking MEDROL for a long period of time. Taking methylprednisolone will increase the risk of developing a growing pressure in the skull (high intracranial pressure).
- Your healthcare professional may need to monitor the heart if methylprednisolone is given to a prematurely born baby.

**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

**Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.**

**The following may interact with MEDROL:**

- **Medicines used to:**
  - treat glaucoma and epilepsy such as acetazolamide
  - prevent or treat nausea and vomiting such as aprepitant or fosaprepitant
  - treat cancer such as aminoglutethimide or cyclophosphamide
  - “thin” the blood or prevent blood clotting (anticoagulants such as acenoumarol, phenindione and warfarin)
  - treat myasthenia gravis (a muscle condition) such as distigmine and neostigmine

- treat bacterial and fungal infections (antibiotics and antifungals) such as ketoconazole, itraconazole, amphotericin B, erythromycin, clarithromycin, troleandomycin, rifampin, rifampicin and rifabutin)
- treat inflammation such as aspirin and non-steroidal anti-inflammatory medicines (also called NSAIDs) like ibuprofen
- treat epilepsy such as barbiturates, carbamezipine, phenobarbital, phenytoin and primidone
- treat heartburn and acid indigestion such as cimetidine
- treat heart problems or high blood pressure as digoxin and diltiazem
- reduce extra fluid in the body (water pills or diuretics)
- for hormone replacement therapy or hormonal oral contraceptive (such as ethinyl estradiol and norethindrone)
- treat high cholesterol (such as cholestyramine)
- treat HIV infections such as indinavir or ritonavir
- in surgery to block signals between nerves and muscles (neuromuscular blocking agents) such as pancuronium or vecuronium
- help prevent organ rejection such as cyclosporine and tacrolimus
- vaccines. Tell your healthcare professional if you have recently had, or are about to have any vaccination
- treat diabetes
- treat tuberculosis (such as isoniazid)

#### **How to take MEDROL:**

##### **Usual dose:**

Between 4 mg to 48 mg daily, based on your condition and how severe it is.

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

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

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

MEDROL should not be stopped suddenly. Do not stop taking MEDROL without talking to your healthcare professional.

##### **Overdose:**

If you think you, or a person you are caring for, have taken too much MEDROL, contact a healthcare professional, 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. However, if it is almost time for the next dose, skip the missed dose and take your next scheduled dose. Do not take two doses to make up for a missed one.

## What are possible side effects from using MEDROL?

These are not all the possible side effects you may have when taking MEDROL. If you experience any side effects not listed here, tell your healthcare professional.

### Infections:

MEDROL may:

- hide symptoms of infections
- reactivate dormant infections
- induce infections due to lowered body resistance

### Allergic Reactions:

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

### Heart problems:

- heart failure
- heart attack
- arrhythmia (irregular heartbeat)
- high and low blood pressure
- blood clots
- thrombophlebitis (vein inflammation)
- thrombosis (blood clot within a blood vessel)
- cardiac arrest
- pediatric hypertrophic cardiomyopathy (thickening of heart muscle)
- facial blushing

### Skin problems:

- 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 problems:

- 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 hypothalamic 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
- lowered carbohydrate (sugar) tolerance
- buildup of acid in the body (metabolic acidosis)
- sodium and fluid retention

**Gastrointestinal problems:**

- 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

**Liver problems:**

- enlarged liver

**Musculoskeletal problems:**

- 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
- aseptic necrosis (tissue death)

**Nervous system problems:**

- 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
- inflammation of nerves (neuritis)
- nerve damage
- abnormal amount of fat deposit around the spine (epidural lipomatosis)

**Eye problems:**

- cataracts
- increased eye pressure
- glaucoma
- protrusion of the eyeball
- retinal detachment

**Psychiatric problems:**

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

**Sexual Function/Reproduction problems:**

- irregular periods
- increased or decreased motility and number of sperm

**Blood problems:**

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

**Other:**

- fatigue, hiccups, swelling
- Tumor lysis syndrome (TLS): This is the sudden, rapid death of cancer cells due to treatment. TLS can cause life-threatening kidney failure and heart problems.

<b>Serious side effects and what to do about them</b>			
<b>Symptom / effect</b>	<b>Talk to your healthcare professional</b>		<b>Stop taking drug and get immediate medical help</b>
	<b>Only if severe</b>	<b>In all cases</b>	
<b>Stomach ulcers</b> (burst or bleeding ulcers): symptoms of which are stomach pain, black or bloodstained stools and/or vomiting blood			√
<b>Flare up of a previous Tuberculosis:</b> symptoms of which could be coughing blood or pain in the chest			√
Infection: symptoms might include a raised temperature and feeling unwell.		√	
<b>High blood pressure:</b> headaches or generally feeling unwell		√	
Swelling		√	
Cramps and spasms		√	
Vision changes		√	
<b>Mental problems:</b> feeling high (mania), mood swings, depression, suicidal thinking, agitation, anxiety, trouble sleeping, confusion, losing your memory		√	
Feeling, seeing or hearing things which do not exist.		√	
Increased thirst and urination		√	
Fast/pounding or irregular heartbeat		√	
Acne	√		
Poor wound healing	√		
Thinning of skin	√		
Increased hair growth	√		
<b>Congestive heart failure:</b> Dizziness, fatigue, weakness, shortness of breath			√
Muscle weakness			√
Bone and joint pain			√
Prone to bone fracture or breaking			√



If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

### **Reporting Side Effects**

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

*NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.*

### **Storage:**

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.

### **If you want more information about MEDROL:**

- Talk to your healthcare professional

Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the manufacturer's website <http://www.pfizer.ca>, or by calling 1-800-463-6001.

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