

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);
- 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.

Immune system:

- 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 or immunized/vaccinated for these infections previously.
- MEDROL may:
 - hide symptoms of infection;
 - worsen symptoms of existing infections;
 - cause new infections due to lowered body resistance.

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 acenocoumarol, 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, carbamezpine, 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.

Side effects of MEDROL include:

- facial blushing
- skin problems such as reddish spot containing blood that appears in skin, acne, rash, redness, itchy skin, dry/scaly skin, increased sweating, lightening or darkening of an area of skin, abscess (pocket of pus), thinning of hair, stretch marks
- abnormal hair growth
- gastrointestinal problems such as nausea, vomiting, diarrhea, altered sense of taste, abdominal pain, bloating, abnormal appetite, indigestion.
- loss of muscle mass, muscle weakness
- muscle cramps and spasms
- nervous system problems (including nerve inflammation and damage) such as headache, pain and tenderness, impaired sensation, strength and reflexes, sensation of heat, cold, numbness, sensation of tingling, tickling, prickling, or burning of a person's skin, vertigo, dizziness, forgetfulness, twitching, drowsiness, ringing in ears, tremors
- abnormal behaviour such as anxiety, nervousness, confusion, euphoria (intense feelings of well-being, elation, happiness, excitement and joy), personality changes, irritability, mood swings/emotional instability, mania (feeling high), drug dependence, trouble sleeping
- irregular periods
- memory loss

MEDROL can cause abnormal blood test results. Your healthcare professional will decide when to perform the tests and interpret the results.

| Serious side effects and what to do about them | | | |
|---|--------------------------------------|--------------|---|
| Symptom / effect | Talk to your healthcare professional | | Stop taking drug and get immediate medical help |
| | Only if severe | In all cases | |
| UNKNOWN FREQUENCY | | | |
| Abnormal (high or low) blood pressure: headaches, dizziness, fainting, light-headedness, blurred | | √ | |

| Serious side effects and what to do about them | | | |
|--|--------------------------------------|--------------|---|
| Symptom / effect | Talk to your healthcare professional | | Stop taking drug and get immediate medical help |
| | Only if severe | In all cases | |
| vision, nausea, vomiting, fatigue (may occur when you go from lying or sitting to standing up), racing pulse, or heart palpitations. | | | |
| Allergic reactions: rash, hives, swelling of the face, lips, tongue, or throat, itching, difficulty swallowing, difficulty breathing, drop in blood pressure, dizziness, fainting, wheezing, nausea, or vomiting. | | | √ |
| Arrhythmia (abnormal heart rhythms): fast, slow, pounding, or irregular heartbeat | | √ | |
| Aseptic necrosis (tissue death): progressive or persistent pain, limited range of motion in a joint or limb, joint pain, swelling, tenderness, weakness, or joint stiffness. | | | √ |
| Bladder problems: not reaching the bathroom in time, or having to pee multiple times during the night. | | √ | |
| Bleeding, poor wound healing | √ | | |
| Blood clots: swelling, pain or tenderness, usually in the arm or leg, tingling, numbness, pale skin, muscle pain, or muscle spasms. | | | √ |
| Breathing problems or breathing stops | | | √ |
| Cardiac arrest (heart stops beating suddenly): fatigue, loss of consciousness, dizziness, nausea, chest pain, shortness of breath, or pounding heart beat. | | | √ |
| Charcot joint disease (foot and ankle issues due to nerve-related problems): joint swelling, foot pain, or heat or redness over the joint. | | √ | |
| Coma (deep loss of consciousness) | | | √ |
| Cushingoid syndrome (increased cortisol levels): weight gain, rounded “moon” face, thin and fragile skin, | √ | | |

| Serious side effects and what to do about them | | | |
|---|--------------------------------------|--------------|---|
| Symptom / effect | Talk to your healthcare professional | | Stop taking drug and get immediate medical help |
| | Only if severe | In all cases | |
| easy bruising, fatigue, headache, or weak muscles. | | | |
| Depression (sad mood that won't go away): difficulty sleeping, sleeping too much, changes in appetite or weight, feelings of worthlessness, guilt, regret, helplessness or hopelessness, withdrawal from social situations, family, gatherings and activities with friends, or reduced libido (sex drive). | √ | | |
| Diabetes (high blood sugar) or decreased sugar tolerance : increased thirst, increased urination, increased appetite, or have blurry vision. | | √ | |
| Edema (swelling or fluid retention): unusual swelling of the arms, hands, legs, feet and ankles, face or airway passages. | | √ | |
| Epidural lipomatosis (fat build-up around the spine): back pain, weakness, loss of sensation, or reflexes that are too slow or too fast. | | √ | |
| Eye problems including cataracts : retina pulled away from normal position, double vision, blurry vision, eye pain, increased pressure in the eyes, blindness in one or both eyes, or bulging eyes. | | | √ |
| Flare up of a previous tuberculosis : cough that does not go away, fever, loss of weight, coughing blood, or pain in the chest. | | | √ |
| Fractures (broken bones): pain, bruising, swelling over the broken bone, or sudden pain that is worse when walking or standing. | | √ | |
| Heart attack : pressure or squeezing pain between the shoulder blades, in the chest, jaw, left arm or upper abdomen, shortness of breath, dizziness, fatigue, light-headedness, | | | √ |

| Serious side effects and what to do about them | | | |
|--|--------------------------------------|--------------|---|
| Symptom / effect | Talk to your healthcare professional | | Stop taking drug and get immediate medical help |
| | Only if severe | In all cases | |
| clammy skin, sweating, indigestion, anxiety, feeling faint, or irregular heartbeat. | | | |
| Heart failure: dizziness, fatigue, weakness, shortness of breath, fainting, irregular heart rate, or fast pounding heart beat. | | | √ |
| Increased intracranial pressure (pressure within the skull with swelling) | | | √ |
| Infections: symptoms of an existing infection worsen, reactivation of a dormant infection, persistent fever, cough, feeling unwell, sore throat, painful urination, eye pain, eye discharge | | | √ |
| Injection site infections/reactions: blistering, pain, skin changes or depressions, tenderness, warmth in the area around the injection, or inflammation. | √ | | |
| Kaposi's sarcoma (cancer that causes tumours in the blood vessels and skin): slightly elevated purple, pink, brown, black, blue, or red blotches or bumps anywhere on the skin or in the mouth and/or throat. | | | √ |
| Liver problems including liver injury and hepatitis (inflammation of the liver): yellowing of the skin or whites of eyes, urine turns dark, nausea, vomiting, lower stomach pain, fatigue, fever, light-coloured stool, or unusual tiredness. | | √ | |
| Meningitis (infection of membranes that surround brain and spinal cord): fever, nausea, vomiting, headache, stiff neck, extreme sensitivity to bright light, confusion, seizures, sleepiness, difficulty waking, no appetite or thirst, or skin rash. | | | √ |
| Metabolic acidosis (high level of acid in the blood): fatigue, | | | √ |

| Serious side effects and what to do about them | | | |
|--|--------------------------------------|--------------|---|
| Symptom / effect | Talk to your healthcare professional | | Stop taking drug and get immediate medical help |
| | Only if severe | In all cases | |
| abdominal pain, confusion, dizziness, loss of appetite, headache, nausea, vomiting, weakness, or increased heart rate. | | | |
| Osteoporosis (thin, fragile bones): broken bones, joint pain, bone pain, or back pain that gets worse when standing or walking. | | √ | |
| Pancreatitis or esophagitis (inflammation of the pancreas or esophagus): abdominal pain, nausea, vomiting, hard or painful swallowing, heartburn, fever, rapid heart beat, or tenderness when touching the abdomen. | | | √ |
| Perforation of the bowel (a hole in the intestines): abdominal pain, feeling bloated, nausea, vomiting, chills, or fever. | | | √ |
| Peritonitis (inflammation of the stomach lining): severe abdominal pain that is worse when you move, feeling sick to your stomach or throwing up, fever, or swollen belly. | | | √ |
| Pheochromocytoma (adrenal gland tumour): high blood pressure, sweating, rapid heartbeat, pale appearance, sweating, or headache. | | | √ |
| Schizophrenia or worsening of schizophrenia: hallucinations (feeling, seeing, or hearing things which do not exist), delusions, disorganized or incoherent thinking, feeling paranoid, suspicious, or scared. | | √ | |
| Seizures (fits): loss of consciousness with uncontrollable shaking. | | | √ |
| Skin Cancer (Unusual skin growth): blotches of skin that may be red, purple, brown or black and may be raised. | | | √ |
| Stomach ulcers (burst or bleeding ulcers): stomach pain, bleeding from the rectum, black or bloodstained | | | √ |

| Serious side effects and what to do about them | | | |
|--|--------------------------------------|--------------|---|
| Symptom / effect | Talk to your healthcare professional | | Stop taking drug and get immediate medical help |
| | Only if severe | In all cases | |
| stools, vomiting blood, loss of appetite, or weight loss. | | | |
| Suicidal thoughts or actions | | | √ |
| Suppression of hypothalamic pituitary-adrenal axis: (body's responses to natural stress do not work properly): fatigue, depression and anxiety, difficulty sleeping, weakness, or loss of muscle mass. | | √ | |
| Tendon rupture (particularly of the Achilles tendon): a snap or popping sound with severe pain at the site of the break, bruising, or inability to use the arm or leg with the break. | | | √ |
| Thinning of skin, fragile skin | √ | | |
| Tumour lysis syndrome (sudden, rapid death of cancer cells due to the treatment): life-threatening kidney failure and heart problems, nausea, shortness of breath, irregular heartbeat, heart rhythm disturbances, lack of urination, clouding of urine, muscle spasms, muscle twitching, tiredness, joint pain, severe muscle weakness, or seizures. | | | √ |

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.

This leaflet was prepared by Pfizer Canada ULC.

Last Revised: JAN 27, 2025