Patient Medication Information

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

Pr SOLU-MEDROL®

methylprednisolone sodium succinate for injection

This Patient Medication Information is written for the person who will be given **SOLU-MEDROL**. This may be you or a person you are caring for. Read this information carefully. Keep it as you may need to read it again.

This Patient Medication Information is a summary. It will not tell you everything about this medication. If you have more questions about this medication or want more information about **SOLU-MEDROL**, talk to a healthcare professional.

What SOLU-MEDROL is used for:

SOLU-MEDROL is used in adults and children to treat many conditions. These include allergic reactions and inflammation.

How SOLU-MEDROL works:

SOLU-MEDROL contains a corticosteroid hormone. It decreases the body's immune response to certain diseases and reduces inflammation.

The ingredients in SOLU-MEDROL are:

Medicinal ingredient: Methylprednisolone sodium succinate

Non-medicinal ingredients:

- For SOLU-MEDROL (plain vials): Dibasic sodium phosphate dried and monobasic sodium phosphate anhydrous. Diluent for SOLU-MEDROL (plain vials): Bacteriostatic water for injection, which contains benzyl alcohol.
- For SOLU-MEDROL (two-compartment ACT-O-VIAL system): Dibasic sodium phosphate dried and monobasic sodium phosphate anhydrous. The 40 mg strength also contains lactose produced from cow's milk. Diluent for SOLU-MEDROL (two compartment ACT-O-VIAL system): Sterile water for injection.

SOLU-MEDROL comes in the following dosage forms:

SOLU-MEDROL comes in plain vials:

- Vial with sterile powder: 500 mg/vial, and 1 g/vial

SOLU-MEDROL also comes in a two-compartment ACT-O-VIAL system:

- Compartment with sterile powder: 40 mg/vial, 125 mg/vial, 500 mg/vial, and 1 g/vial

- Compartment with diluent

Do not use SOLU-MEDROL if:

- you are allergic to methylprednisolone sodium succinate, to any other steroid medicine or any of the other ingredients in SOLU-MEDROL;
- you are lactose intolerant. The 40 mg strength of SOLU-MEDROL in the two-compartment ACT-O-VIAL system contains lactose.
- you have a fungal infection or any untreated infection
- you have recently received a type of vaccine called a live or live-attenuated vaccine. Do not receive this vaccine during treatment with SOLU-MEDROL.
- you have a blood condition called idiopathic thrombocytopenic purpura if SOLU-MEDROL is given to you through injection into your muscle. This condition is when you have a low blood platelet count.

SOLU-MEDROL (plain vials) should not be used in premature and low-birth infants. The diluent contains benzyl alcohol which can cause serious side effects and death.

SOLU-MEDROL should not be injected into your spine or brain (intrathecal or epidural).

Except for short-term or emergency use such as severe allergic reactions, do not use SOLU-MEDROL if you have:

- viral diseases like vaccinia (cowpox), varicella (chickenpox), and herpes simplex of the eye
- a serious lung infection (tuberculosis)
- a serious mental disorder (psychoses)
- Cushing's syndrome (a condition caused by excess corticosteroids)
- a stomach ulcer
- kidney problems

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

- have an infection (such as herpes simplex, chicken pox, tuberculosis, threadworm;
- have recently had or are about to have any vaccine;
- recently had heart problems such as a heart attack, heart failure or heart disease;
- have bleeding or blood clotting problems;
- have brittle bone disease (osteoporosis);
- have high blood pressure;
- have water retention (edema);
- have or had seizures or other nervous system problems;
- have thyroid problems;
- have muscle pain or muscle weakness (such as myasthenia gravis);
- have a tumour of the adrenal glands (pheochromocytoma);
- have certain eye diseases such as glaucoma, cataracts, herpes infection or any problems with the retina;
- have a condition known as systemic sclerosis, in which your body makes too much of a protein called collagen.

- have kidney disease;
- have liver disease such as cirrhosis;
- have diabetes or high blood sugar;
- have certain mental or mood conditions (such as depression);
- have stomach or gut problems (such as ulcer or ulcerative colitis);
- have low blood potassium or calcium;
- have Cushing's disease (caused by an excess of cortisol hormone);
- have a weak immune response. Tell your healthcare professional if you suspect an infection has occurred, as corticosteroids (such as SOLU-MEDROL) can make infections more likely and may mask their signs;
- had any prior use of SOLU-MEDROL.

Other warnings you should know about:

SOLU-MEDROL can cause serious side effects, including:

- **Kaposi's sarcoma** (skin cancer): Kaposi's sarcoma has been reported with corticosteroid therapy, such as SOLU-MEDROL. Stopping treatment of SOLU-MEDROL may result in signs of this cancer going away.
- **Pheochromocytoma** (tumour of the adrenal glands): This tumour has been reported with corticosteroid therapy, such as SOLU-MEDROL. Pheochromocytoma may cause death.
- **Epidural lipomatosis** (fat deposition on or outside the lining of the spine): 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 SOLU-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 SOLU-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.
- You should tell your healthcare professional if you are breast-feeding or planning to breastfeed as small amounts of corticosteroid medicines (such as SOLU-MEDROL) may get into breast milk.

Male fertility: Taking SOLU-MEDROL may affect male fertility.

Stopping treatment: Talk to your healthcare professional before stopping SOLU-MEDROL. If you suddenly stop taking SOLU-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.

Immune system:

- If you or your child is exposed to measles or chickenpox during treatment with SOLU-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.
- SOLU-MEDROL may:
  - hide symptoms of infection;
  - worsen symptoms of existing infections;
  - cause new infections due to lowered body resistance.

Skin:

- Dents/holes may appear at the site of injection.
- Tell your healthcare professional you are taking SOLU-MEDROL since it can affect the results of skin tests.

Driving and using machines: SOLU-MEDROL may cause dizziness, vertigo, vision problems and fatigue. If you experience these side effects, you should not drive or operate machinery.

Children (less than 18 years of age):

- Children may experience a decrease in the speed of their growth. The healthcare professional will prescribe the lowest dose to minimize this risk.
- The healthcare professional will conduct frequent tests on the child if they are taking SOLU-MEDROL for a long period of time. Taking methylprednisolone for a long period of time increases the risk of developing a high intracranial pressure (growing pressure in skull).
- If methylprednisolone is given to a prematurely born baby, monitoring of the heart may be needed.
- SOLU-MEDROL (plain vials) is not recommended to be used in premature and low-birth infants. The diluent contains benzyl alcohol which has been reported to cause “gasping syndrome” that may result in death.

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 SOLU-MEDROL:

Medicines used to:

- treat cancer such as cyclophosphamide
- prevent or relieve a sudden worsening of shortness of breath and wheezing (beta2 agonists) such as salbutamol, budesonide and salmeterol
- treat bacterial and fungal infections (antibiotics and antifungals) such as rifampin, itraconazole, clarithromycin, ketoconazole, troleandomycin, erythromycin and amphotericin B
- treat myasthenia gravis (a muscle condition) such as neostigmine and pyridostigmine
- “thin” the blood or prevent blood clotting (anticoagulants) such as acenocoumarol, warfarin or heparin
- treat epilepsy such as phenobarbital, phenytoin or carbamazepine
- treat diabetes such as insulin, glibenclamide or metformin
- prevent or treat nausea and vomiting associated with cancer chemotherapy treatment such as

aprepitant or fosaprepitant
- treat high cholesterol such as cholestyramine
- treat tuberculosis such as isoniazid
- 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
- treat Cushing's syndrome, breast or ovarian cancer (aromatase inhibitors) such as aminoglutethimide
- treat heart problems or high blood pressure such as digoxin, diltiazem, amlodipine or quinapril
- reduce extra fluid in the body (diuretics, also know as "water pills") such as furosemide
- help prevent organ rejection such as cyclosporine or tacrolimus
- to treat inflammatory diseases (including rheumatoid arthritis) such as azathioprine or methotrexate
- treat anxiety or mental health disorders/mental illnesses (like diazepam or clozapine)
- treat diarrhea
- vaccines. Tell your healthcare professional if you have recently had, or are about to have any vaccination
- treat inflammation such as aspirin and non-steroidal anti-inflammatory medicines (also called NSAIDs) such as ibuprofen
- for hormone replacement therapy or hormonal oral contraceptives such as ethinyl estradiol and norethindrone

Do not eat grapefruit or drink grapefruit juice while taking SOLU-MEDROL.

How SOLU-MEDROL is given:

- SOLU-MEDROL will be given to you by your healthcare professional. They will decide to give SOLU-MEDROL to you by either:
  - Infusion into your vein (intravenous infusion) over 1 hour; or
  - Slow injection into your vein (intravenous injection); or
  - Injection into your muscle (intramuscular).
- Your healthcare professional will decide on the site of injection, as well as how much of the medicine and how many injections you will receive.
- The healthcare professional will prescribe the lowest possible dose for the minimum period of time.

Usual dose:

The dose you will receive depends on:

- the condition you are being treated for;
- the severity of your condition;
- your response to the treatment; and
- your exposure to physical stress like infection, surgery or injury.

Overdose:

If you think you, or a person you are caring for, have been given too much SOLU-MEDROL, contact a healthcare professional, hospital emergency department, regional poison control centre or Health

Canada's toll-free number, 1-844 POISON-X (1-844-764-7669) immediately, even if there are no signs or symptoms.

Possible side effects from using SOLU-MEDROL:

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

Side effects of SOLU-MEDROL may include:

- facial blushing;
- skin problems such as reddish spot containing blood that appears in skin, acne, red or tender bumps on your skin, rash, redness, itchy skin, dry and scaly skin, increased sweating, lightening or darkening of an area of skin, abscess (pocket of pus), thinning of hair, and stretch marks;
- abnormal hair growth;
- gastrointestinal problems such as nausea, vomiting, diarrhea, altered sense of taste, abdominal pain, bloating, abnormal appetite, and indigestion;
- loss of muscle mass and muscle weakness;
- muscle cramps and spasms;
- nervous system problems (including nerve inflammation and damage) such as headache, pain, 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, and 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, and trouble sleeping;
- irregular periods;
- memory loss;
- suppressed growth in children.

SOLU-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

Frequency/Side Effect/Symptom	Talk to your healthcare professional		Stop taking this drug and get immediate medical help
	Only if severe	In all cases	
Abnormal (high or low) blood pressure: headaches, dizziness, fainting, light-headedness, blurred 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			**√**

Frequency/Side Effect/Symptom	Talk to your healthcare professional		Stop taking this drug and get immediate medical help
	Only if severe	In all cases	
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.			√
Cardiomyopathy in children (thickening of the heart muscle): fatigue, cough, shortness of breath, swelling, poor growth, or difficulty gaining weight.		√	
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, easy bruising, fatigue, headache, or weak muscles.	√		
Depression (sad mood that won't go	√		

Frequency/Side Effect/Symptom	Talk to your healthcare professional		Stop taking this drug and get immediate medical help
	Only if severe	In all cases	
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, clammy skin, sweating, indigestion, anxiety, feeling faint, or irregular heartbeat.			**√**

Frequency/Side Effect/Symptom	Talk to your healthcare professional		Stop taking this drug and get immediate medical help
	Only if severe	In all cases	
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, abdominal pain, confusion, dizziness, loss of appetite, headache, nausea, vomiting, weakness, or increased heart rate.			√

Frequency/Side Effect/Symptom	Talk to your healthcare professional		Stop taking this drug and get immediate medical help
	Only if severe	In all cases	
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, or headache.			√
Rhabdomyolysis (breakdown of damaged muscle): muscle pain that you cannot explain, muscle tenderness or weakness, dark urine.		√	
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			√

Frequency/Side Effect/Symptom	Talk to your healthcare professional		Stop taking this 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 (canada.ca/drug-device-reporting) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

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

Storage:

- **Before Reconstitution:** Store SOLU-MEDROL sterile powder at room temperature (15° - 30°C). Protect from light.
- **After Reconstitution:** Store reconstituted solution at room temperature (15° - 30°C). Use reconstituted solution within 48 hours after mixing. Protect from light.
- Keep out of reach and sight of children.

If you want more information about SOLU-MEDROL:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes the Patient Medication Information by visiting the Health Canada Drug Product Database 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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