

## **PATIENT MEDICATION INFORMATION**

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

Pr **SOLU-MEDROL**<sup>®</sup>

Pr **SOLU-MEDROL**<sup>®</sup> ACT-O-VIALS<sup>®</sup>

#### **Methylprednisolone sodium succinate for injection USP**

Read this carefully before you start taking **SOLU-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 **SOLU-MEDROL**.

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

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

#### **How does SOLU-MEDROL work?**

SOLU-MEDROL is a synthetic corticosteroid. It decreases the body's reaction to some severe conditions and reduces inflammation.

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

Medicinal ingredients: methylprednisolone sodium succinate

Non-medicinal ingredients: Dibasic sodium phosphate dried and monobasic sodium phosphate anhydrous. SOLU-MEDROL ACT-O-VIALS, 40 mg, also contains lactose produced from cow's milk.

Diluent for SOLU-MEDROL (plain vials): Bacteriostatic Water for Injection, which contains benzyl alcohol. Medicines with benzyl alcohol are contraindicated in premature infants and should be used with caution in children.

Diluent for the SOLU-MEDROL ACT-O-VIALS: Sterile Water for Injection.

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

SOLU-MEDROL comes in plain vials:

- Vial with sterile powder: 500 mg, 1 g

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

- Compartment with sterile powder: 40 mg, 125 mg, 500 mg, 1 g
- Compartment with diluent

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

- you are allergic to methylprednisolone sodium succinate or any ingredient in this medicine.
- you are lactose intolerant. SOLU-MEDROL ACT-O-VIALS 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 (low platelet count), for intramuscular use.

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.

This medicine is not injection via the spinal cord 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 take 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); **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.**
- 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 (osteoporosis)
- have high blood pressure
- have water retention (oedema)
- have or had seizures or other nervous system problems
- have thyroid problems
- have muscle pain or muscle weakness (such as myasthenia gravis)
- have a tumor 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 (high blood sugar)
- have certain mental or mood conditions (such as depression)

- have stomach or gut problems (ulcer, ulcerative colitis)
- have low 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 can make infections more likely and may mask their signs
- had any prior use of SOLU-MEDROL.

**Other warnings you should know about:**

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

- skin cancer (Kaposi's sarcoma): 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.
- tumor of the adrenal glands (pheochromocytoma). This tumor has been reported with corticosteroid therapy, such as SOLU-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 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.
- If you are breastfeeding or planning to breastfeed, tell your healthcare professional.

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

**Stopping treatment:** If you suddenly stop taking SOLU-MEDROL, you may experience:

- Serious adrenal insufficiency. Adrenal insufficiency 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:**

- 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 provider 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.

**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/antifungals such as rifampin, itraconazole, clarithromycin, ketoconazole, troleandomycin\*, erythromycin and amphotericin B)
    - prevent the elimination of a neurotransmitter, acetylcholine (such as neostigmine and pyridostigmine)
    - prevent blood clotting (such as warfarin or heparin)
    - treat epilepsy (such as phenobarbital, phenytoin or carbamazepine)
    - treat diabetes (such as insulin, glibenclamide or metformin)
    - treat high blood pressure (such as amlodipine or quinapril)
    - prevent 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
    - treat Cushing's syndrome, breast or ovarian cancer (aromatase inhibitors such as aminoglutethimide\*)
    - treat heart problems (such as digoxin, calcium channel blockers)
    - reduce extra fluid in the body (diuretics 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
- \*not marketed in Canada
- Vaccines
  - Neuromuscular Blocking Agents (agents that block signals between nerves and muscles such as pancuronium)
  - Aspirin and non-steroidal anti-inflammatory medicines (also called NSAIDs) such as ibuprofen
  - Sympathomimetic Agents (agents that mimic the effects of adrenaline like salbutamol, used to treat asthma)
  - Hormone replacement therapy or hormonal oral birth control

Do not drink grapefruit juice while taking SOLU-MEDROL.

**How to take SOLU-MEDROL:**

- 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:
  - type of condition being treated;
  - severity of the 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 taken too much SOLU-MEDROL, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

**What are 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.

**Infections:**

SOLU-MEDROL may:

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

**Heart problems:**

- Low blood pressure
- Fainting
- Blood clots
- facial blushing
- Thrombophlebitis (vein inflammation)
- Pediatric hypertrophic cardiomyopathy (thickening of heart muscle)

**Skin problems:**

- Ecchymoses (spots caused by ruptured blood vessels)
- Petechiae (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 the skin

- Abscess
- Thinning scalp hair
- Injection site infections/reactions: blistering, pain, skin changes/depressions, tenderness, warmth in the area around the injection

#### Endocrine and metabolism problems:

- Development of Cushingoid state (abnormal bodily condition caused by excess corticosteroids)
- Moon face (enlargement of face and forehead)
- Weight gain
- Abnormal fat deposits
- hypopituitarism (a condition in which your pituitary gland fails to produce one or more of its hormones or does not produce enough of them).
- 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)

- 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.
- Suppression of growth in children
- Sodium retention and excretion
- Increased urination
- Decreased carbohydrate (sugar) tolerance
- New symptoms of diabetes, need for higher doses of insulin or sugar lowering pills in diabetics

#### Gastrointestinal problems:

- Stomach ulcer or bleeding
- Inflammation of the pancreas, esophagus, peritoneum
- Perforation of the bowel
- Nausea, vomiting, diarrhea

- Altered sense of taste (with rapid administration of large doses)
- Abdominal pain, bloating
- Bowel/bladder dysfunction
- Increased or decreased appetite

#### Liver problems:

- Enlarged liver
- Liver injury

- Hepatitis (liver inflammation)

#### Musculoskeletal problems:

- Muscle disease
- Muscle pain
- Loss of muscle mass
- Malaise (feeling of general discomfort or uneasiness)
- Aseptic necrosis (tissue death)

- Fractures caused by disease, spine fractures
- Tendon rupture, particularly of the Achilles tendon
- Charcot joint disease (foot and ankle problems)

#### Nervous system problems:

- Increased pressure within the skull with oedema and inflammation of the optic nerve
- Headache

- Pain and tenderness
- Impaired sensation, strength and reflexes
- Sensation of tingling, tickling, prickling or burning of a person's skin

- Vertigo, dizziness
- Meningitis (inflammation of membranes that surround brain and spinal cord)

- Amnesia

Eye problems:

- Protrusion of the eyeball

- Blindness

Psychiatric problems:

- Emotional instability
- Euphoria (intense feelings of well-being, elation, happiness, excitement, and joy)
- Personality changes
- Delusion

- Hallucination
- Confusion
- Schizophrenia
- Irritability

Sexual Function/Reproduction:

- Irregular periods

- Increased or decreased mobility and number of sperm

Blood problems:

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

Other:

- Hiccups

- 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	
<b>UNKNOWN</b>			
<b>Convulsion:</b> seizure, shaking or fits			√
Cramps and spasms		√	
<b>Diabetes:</b> Increased thirst/urination		√	
Easy bruising/bleeding			√
<b>Edema:</b> Fluid retention, swelling		√	
<b>Eye problems:</b> failing eyesight, blurry vision, eye pain, increased pressure in your eyes		√	
<b>Epidural lipomatosis</b> (fat buildup on outside of spine): back pain, weakness, loss of sensation or reflexes that are too slow or too fast			√
<b>Flare up of a previous Tuberculosis:</b> symptoms of which could be coughing blood or pain in the chest			√
<b>Heart failure:</b> Shortness of breath,			√

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	
fatigue, weakness, dizziness, irregular or fast pounding heart beat			
<b>High blood pressure:</b> headaches or generally feeling unwell		√	
<b>Hormonal changes:</b> Irregular menstrual periods, unusual hair growth	√		
<b>Kaposi's sarcoma</b> (a type of skin cancer): slightly elevated purple, pink, brown, black, blue, or red blotches or bumps anywhere on the skin or in the mouth and/or throat			√
<b>Mental problems:</b> mood swings, depression, suicidal thinking, agitation, anxiety, trouble sleeping		√	
Muscle weakness			√
<b>Osteoporosis</b> (thin, fragile bones): broken bones, bone pain, back pain that gets worse when standing or walking			√
<b>Pheochromocytoma</b> (adrenal gland tumour): symptoms often include high blood pressure, sweating, rapid heartbeat, and headache			√
<b>Serious allergic reaction:</b> symptoms of which include rash, itching/swelling (especially of the face/tongue/throat), severe dizziness and trouble breathing			√
<b>Signs of infection:</b> persistent fever/cough/sore throat, painful urination, eye pain/discharge		√	
<b>Stomach ulcers</b> (burst or bleeding ulcers): symptoms of which are stomach pain, bleeding from the rectum, black or bloodstained stools and/or vomiting blood			√
Tendon or joint pain			√
Thinning skin	√		
Wounds that are slow to heal	√		
<b>Unusual skin growth</b> (nodules or blotches that may be red, purple, brown or black and may be raised)		√	

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:

Keep out of the reach and sight of children.

**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.

### 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 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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