

PART III: CONSUMER INFORMATION

Pr SOLU-MEDROL®
Pr SOLU-MEDROL® ACT-O-VIALS®

methylprednisolone sodium succinate for injection USP

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

ABOUT THIS MEDICATION

What the medication is used for:

SOLU-MEDROL is used in the treatment of various conditions such as allergic reactions or inflammation.

What it does:

SOLU-MEDROL contains a synthetic corticosteroid and is usually used for short periods in severe conditions to decrease inflammation.

When it should not be used:

- in patients who are allergic to this medicine or any ingredient of this medication.
- for fungal infections
- for patients taking live or live, attenuated vaccines
- for injection into the brain or the spine
- for a blood condition called idiopathic thrombocytopenic purpura (low platelet count), if SOLU-MEDROL is administered intramuscularly

Except for short-term or emergency use such as severe allergic reactions, SOLU-MEDROL should also not be given to patients with:

- viral diseases including vaccinia (cowpox), varicella (chickenpox), and herpes simplex of the eye
- tuberculosis
- serious mental disorder (psychoses)
- Cushing's syndrome (abnormal bodily condition caused by excess corticosteroids)
- a stomach ulcer
- altered kidney function

SOLU-MEDROL Plain Vials should not be used in premature infants. However, SOLU-MEDROL ACT-O-VIALS may be used.

Patients taking SOLU-MEDROL should not receive live vaccines.

What the medicinal ingredient is:

methylprednisolone sodium succinate

What the important nonmedicinal ingredients are:

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

When needed, the pH is adjusted with sodium hydroxide.

The diluent for reconstitution of the Plain Vials is 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.

The diluent for reconstitution of the ACT-O-VIALS is Sterile Water for Injection.

What dosage forms it comes in:

SOLU-MEDROL comes in vials containing sterile powder.

The available formulations are:

Plain Vials

- 500 mg Vial
- 1 g Vial

ACT-O-VIALS

- 40 mg ACT-O-VIALS
- 125 mg ACT-O-VIALS
- 500 mg ACT-O-VIALS
- 1 g ACT-O-VIALS

WARNINGS AND PRECAUTIONS

BEFORE you use SOLU-MEDROL talk to your doctor or pharmacist if:

- you have an infection (such as herpes simplex, chicken pox, tuberculosis, threadworm)
- you recently had myocardial infarction (heart attack)
- you have thromboembolic disorders (bleeding or blood clotting problems)
- you have brittle bone (osteoporosis)
- you have high blood pressure (hypertension)
- you have water retention (oedema)
- you have seizures (fits)
- you have thyroid problems
- you have muscle pain or muscle weakness (such as myasthenia gravis)
- you have skin cancer (Kaposi's sarcoma)
- you have certain eye diseases such as glaucoma, cataracts, herpes infection
- you have kidney disease

- you have liver disease
- you have heart disease
- you have diabetes (high blood sugar)
- you have certain mental or mood conditions (such as depression)
- you have stomach or gut problems (ulcer, ulcerative colitis)
- you have low potassium or calcium
- you have Cushing’s disease (caused by an excess of cortisol hormone)
- you have weak immune response
- you have thrombophlebitis (vein inflammation)
- you are pregnant, planning to become pregnant or are breast-feeding (nursing).
- you have any allergies to this medicine or to any of the ingredients of this medication.
- you have a known or suspected sensitivity to cow’s milk.
- you had any prior use of SOLU-MEDROL.
- you have a condition known as systemic sclerosis, in which your body makes too much of a protein called collagen.

INTERACTIONS WITH THIS MEDICATION

Tell your doctor or pharmacist about all prescription and non-prescription medications you are using. The following may interact with SOLU-MEDROL:

- Antibiotics/Antifungals (e.g. rifampin, ketoconazole, toleandomycin, erythromycin and amphotericin B)
- Anticholinesterase (drugs that prevent the elimination of a neurotransmitter, acetylcholine. e.g. neostigmine and pyridostigmine)
- Drugs that prevent blood clotting (e.g. warfarin or heparin)
- Epilepsy medication (e.g. phenytoin)
- Diabetes medication (e.g. insulin or metformin)
- High blood pressure treatment (e.g. amlodipine or quinapril)
- Diuretics (e.g. furosemide)
- Heart medication (e.g. digoxin, calcium channel blockers)
- Vaccines
- Drugs that suppress the immune system (methotrexate or cyclosporine)
- Neuromuscular Blocking Agents (agents that block signals between nerves and muscles. e.g. pancuronium)
- Drugs that act on the nervous system (e.g. diazepam or clozapine)
- Aspirin and non-steroidal anti-inflammatory medicines (also called NSAIDs) such as ibuprofen
- Sympathomimetic Agents (agents that mimic the effects of adrenaline. e.g. salbutamol)
- Drugs to treat high cholesterol (e.g., cholestyramine)
- Drugs to treat diarrhea
- Drugs to treat tuberculosis

- Hormone replacement therapy or hormonal oral contraceptives
- Aromatase inhibitors (drugs to treat breast or ovarian cancer)
- Immunosuppressants (drugs that suppress or reduce the strength of the body's immune system)

Do not drink grapefruit juice while taking SOLU-MEDROL.

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.

PROPER USE OF THIS MEDICATION

SOLU-MEDROL may be administered by intravenous or intramuscular injection or by intravenous infusion, the preferred method for initial emergency use being intravenous injection.

Prepare SOLU-MEDROL Plain Vials or ACT-O-VIALS according to instructions below. Both vial formats are for single dose only.

Prepared SOLU-MEDROL can be used for intravenous or intramuscular injection.

For intravenous infusion, the prepared SOLU-MEDROL products can be further diluted with Dextrose 5% Water or 0.9% Sodium Chloride or Dextrose 5% in 0.45% Sodium Chloride.

Before use, inspect prepared SOLU-MEDROL for any particulate matter and discoloration.

Any prepared SOLU-MEDROL should be used within 48 hrs.

DIRECTIONS FOR USING THE PLAIN VIAL

SOLU-MEDROL 500 mg vial: add 8 ml Bacteriostatic Water for Injection USP.

SOLU-MEDROL 1g vial: add 16 ml Bacteriostatic Water for Injection USP.

DIRECTIONS FOR USING THE ACT-O-VIAL SYSTEM

1. Press down on plastic activator to force diluent into the lower compartment.



2. Gently shake to mix the solution.



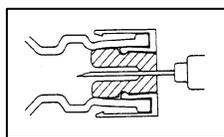
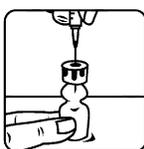
3. Remove plastic tab covering centre of stopper.



4. Sterilize top of stopper with an antiseptic (ex. alcohol wipe).



5. Insert needle **squarely through centre** of stopper until tip is just visible.



6. Invert vial and withdraw dose.

Usual dose:

Initial dosage will vary from 10 to 500 mg depending on the clinical problem being treated. Larger doses may be required for short-term management of severe, acute conditions. Therapy may be initiated by administering SOLU-MEDROL intravenously over a period of at least 5 minutes (e.g., doses up to 250 mg) to at least 30 minutes (e.g., doses greater than 250 mg). Subsequent doses may be given intravenously or intramuscularly at intervals dictated by the patient's response and clinical condition.

Corticosteroid therapy is used in combination with, and not replacement for, conventional therapy.

The dose needs to be gradually decreased when the medication needs to be discontinued after several days of treatment.

Overdose:

If an overdose occurs, SOLU-MEDROL can be eliminated through dialysis. Continuous overdosing would require careful gradual reduction of the dose of the medication.

In case of overdose, contact a health care practitioner, hospital emergency department or regional poison control centre immediately, even if there are no symptoms.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

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

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

Potential side effects with SOLU-MEDROL include:

Allergic Reactions:

- Anaphylaxis (a severe, life-threatening allergic reaction)
- Cardiac arrest
- Bronchospasm (narrowing of the airway)
- Rapid swelling of the skin

Cardiovascular:

- Heart failure
- Heart attack
- Arrhythmia (irregular heartbeat)
- Slow heart beat
- High and low blood pressure
- Fainting
- Blood clots
- Thrombophlebitis (vein inflammation)

Dermatologic:

- Thin fragile skin
- Impaired wound healing
- Ecchymoses (spots caused by ruptured blood vessels)
- Petechiae (reddish spot containing blood that appears in skin)
- Skin changes (depressions) at the injection
- Acne
- Rash
- Itchiness
- Dry scaly skin
- Swelling
- Redness
- Increased sweating
- Lightening or darkening of an area of the skin
- Abscess
- Thinning scalp hair
- Injection site infections

Endocrine and Metabolism:

- Development of Cushingoid state (abnormal bodily condition caused by excess corticosteroids)
- Moon face (enlargement of face 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
- Sodium retention and excretion
- Fluid retention
- Increased urination
- Decreased carbohydrate (sugar) tolerance
- New symptoms of diabetes
- Need for higher doses of insulin or sugar lowering pills in diabetics

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
- Bowel/bladder dysfunction
- Increased or decreased appetite
- Peritonitis

Hepatic:

- Enlarged liver
- Liver injury
- Hepatitis

Musculoskeletal:

- Muscle disease
- Muscle weakness
- Muscle pain
- Loss of muscle mass
- Malaise (feeling of general discomfort or uneasiness)
- Osteoporosis
- Aseptic necrosis (tissue death)
- Pathologic fractures
- Vertebral compression fractures
- Tendon rupture, particularly of the Achilles tendon
- Charcot joint disease
- Pain and inflammation of the tissues surrounding the injection site

Neurologic:

- Increased pressure within the skull with oedema and inflammation of the optic nerve
- Seizures
- Headache
- Pain and tenderness
- Impaired sensation, strength and reflexes
- Sensation of tingling, tickling, prickling or burning of a person’s skin

- Vertigo
- Meningitis
- Amnesia
- Dizziness

Ophthalmologic:

- Cataracts
- Protrusion of the eyeball
- Increased intraocular pressure
- Glaucoma
- Blindness.

Psychiatric:

- Mental illness
- Depression
- Emotional instability
- Euphoria (intense feelings of well-being, elation, happiness, excitement, and joy)
- Insomnia (difficulty sleeping)
- Mood swings
- Personality changes
- Thoughts of suicide
- Delusion
- Hallucination
- Confusion
- Schizophrenia
- Anxiety
- Irritability

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: SOLU-MEDROL may cause abnormal liver tests and may suppress reactions to skin tests. SOLU-MEDROL may also cause hiccups and fatigue.

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 rectum, black or bloodstained stools and/or vomiting blood			√

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	
Flare up of a previous Tuberculosis: symptoms of which could be coughing blood or pain in the chest			√
Serious allergic reaction: symptoms of which include rash, itching/swelling (especially of the face/tongue/throat), severe dizziness and trouble breathing			√
Signs of infection (such as persistent fever/cough/sore throat, painful urination, eye pain/discharge)		√	
High blood pressure (symptoms of which may be headaches or generally feeling unwell)		√	
Fast/pounding/irregular heartbeat		√	
Swelling		√	
Cramps and spasms		√	
Vision changes		√	
Increased thirst/urination		√	
Mental/mood changes (such as mood swings, depression, suicidal thinking, agitation, anxiety)		√	
Tendon pain			√
Bone/joint pain			√
Easy bruising/bleeding			√
Pain/redness/swelling at the injection site	√		
Thinning skin	√		
Poor wound healing	√		
Unusual hair growth	√		
Unusual skin growth (nodules or blotches that may be red, purple, brown or black and may be raised)		√	

Before Reconstitution: store SOLU-MEDROL Sterile Powder at room temperature (15° - 30°C). Protect from light. Keep out of the reach and sight of children.

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 the 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 1908C
 - 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 may be obtained by contacting the sponsor, Pfizer Canada Inc., at:

1-800-463-6001

This leaflet was prepared by

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HOW TO STORE IT