

PART III: CONSUMER INFORMATION

Pr DEPO-MEDROL

(methylprednisolone acetate injectable suspension USP)
20 mg/mL, 40 mg/mL, 80 mg/mL injectable suspension

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

ABOUT THIS MEDICATION

What the medication is used for:

DEPO-MEDROL (methylprednisolone) is used in the treatment of various conditions such as allergy or inflammation.

What it does:

DEPO-MEDROL is a corticosteroid hormone (glucocorticoid). It decreases the body's immune response to certain diseases and reduces inflammation.

When it should not be used:

Do not take DEPO-MEDROL if you have:

- allergic reaction to methylprednisolone or any other steroid medicine or any of the ingredients in DEPO-MEDROL; or
- any fungal infection or any untreated infections.
- viral diseases including vaccinia (cowpox), varicella (chicken pox), and herpes simplex of the eye.
- low platelet count.

DEPO-MEDROL should not be given to premature infants because the formulation contains benzyl alcohol.

Patients taking DEPO-MEDROL should not receive live vaccines.

What the medicinal ingredient is:

Methylprednisolone acetate

What the nonmedicinal ingredients are:

DEPO-MEDROL multi-dose with preservative benzyl alcohol, dibasic sodium phosphate, monobasic sodium phosphate, polyethylene glycol 3350 and polysorbate 80.

DEPO-MEDROL single-use: myristyl-gamma-picolinium chloride and polyethylene glycol 3350.

What dosage forms it comes in:

DEPO-MEDROL is available in the following strengths containing benzyl alcohol as a preservative:

- The 20 mg/mL are supplied in 5 mL vials and packaged in cartons of 1.
- The 40 mg/mL are supplied in 2 mL and 5 mL vials and packaged in cartons of 5's.
- The 80 mg/mL are supplied in 5 mL vials and packaged in cartons of 1.

DEPO-MEDROL is available in a 40 mg/mL and 80 mg/mL, 1 mL vial containing myristyl gamma picolinium chloride (MGPC).

- The 40 mg/mL are supplied in 1 mL vials and packaged in cartons of 10's.
- The 80 mg/mL are supplied in 1 mL vials and packaged in cartons of 5's.

WARNINGS AND PRECAUTIONS

DEPO-MEDROL with preservative benzyl alcohol is not recommended for injection into the joint (intra-synovial or intra-articular injection).

Before taking DEPO-MEDROL, talk to your doctor if you have:

- an infection (such as herpes simplex, chicken pox, tuberculosis, threadworm);
- bleeding problem, blood clotting problem;
- brittle bone (osteoporosis);
- high blood pressure;
- seizures (fits);
- thyroid problem (hypothyroidism);
- muscle pain or weakness (such as myasthenia gravis);
- skin cancer (Kaposi's sarcoma);
- heart problems such as heart failure;
- certain eye diseases such as glaucoma, cataracts; herpes infection;
- kidney disease;
- liver disease such as cirrhosis;
- certain mental or mood conditions (such as depression)
- stomach or gut problems (ulcer, ulcerative colitis);
- low potassium or calcium;
- Cushing's disease (caused by an excess of cortisol hormone)
- weak immune response;
- high blood sugar.

Before you have any operation, tell your doctor, dentist or anesthetist that you are taking DEPO-MEDROL.

Pregnancy and breast feeding

You must tell your doctor if you are pregnant, think you might be pregnant or are trying to become pregnant as this medicine could slow the baby's growth.

You should also tell your doctor if you are breast feeding as small amounts of corticosteroid medicines may get into breast milk.

Children:

Corticosteroids can affect growth in children.

DEPO-MEDROL with preservative benzyl alcohol is not recommended to be used in infants since benzyl alcohol has been reported to cause "gasping syndrome" that may result in death.

INTERACTIONS WITH THIS MEDICATION

Before taking DEPO-MEDROL talk to your doctor about all your other medications, including those you bought without prescription, herbal or natural products. Especially if you are taking the following:

- drugs to treat glaucoma and epilepsy such as acetazolamide
- drugs to prevent or alleviate nausea and vomiting such as aprepitant or fosaprepitant
- drugs to treat cancer such as aminoglutethimide or cyclophosphamide
- drugs to “thin” the blood; anticoagulants such as acenocoumarol, phenindione and warfarin
- drugs to treat myasthenia gravis (a muscle condition) such as distigmine and neostigmine
- antibiotics and antifungals (such as ketoconazole, itraconazole amphotericin B, erythromycin, clarithromycin, troleandomycin, rifampicin and rifabutin)
- aspirin and non-steroidal anti-inflammatory medicines (also called NSAIDs) such as ibuprofen
- drugs to treat epilepsy such as barbiturates, carbamazepine, phenytoin and primidone
- drugs for heartburn and acid indigestion such as cimetidine
- cyclosporine
- drugs for heart problems or high blood pressure such as calcium channel blockers, digoxin and diltiazem
- water pills (diuretics)
- hormone replacement therapy or hormonal oral contraceptives
- drugs to treat HIV infections such as indinavir or ritonavir
- pancuronium or vecuronium – or other medicines called neuromuscular blocking agents which are used in some surgical procedures
- tacrolimus – used following an organ transplant to prevent rejection of the organ
- vaccines – tell your doctor or nurse if you have recently had, or are about to have any vaccination
- drugs to treat diabetes
- drugs to treat tuberculosis
- drugs to treat high cholesterol (cholestyramine)
- 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 Depo-Medrol.

Driving and Using Machines

Side effects, such as dizziness, vertigo, visual disturbance and fatigue are possible after treatment with corticosteroids. If you experience these effects, you should not drive or operate machinery.

PROPER USE OF THIS MEDICATION

DEPO-MEDROL is to be given to you as an injection to the joint (intra-articular or intra-synovial injection), or into a muscle (intramuscular injection) by your health care provider. The dose of DEPO-MEDROL is depending on your condition and how severe it is.

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

DEPO-MEDROL should not be stopped abruptly.

Overdose:

In case of drug 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, DEPO-MEDROL can have side effects although not everybody gets them.

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

Potential side effects with DEPO-MEDROL include:

Allergic Reactions:

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

Cardiovascular:

- heart failure
- heart attack
- arrhythmia (irregular heartbeat)
- high and low blood pressure
- blood clots
- thrombophlebitis (vein inflammation)

Dermatologic:

- 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
- injection site reaction
- lightening or darkening of an area of skin
- abscess
- suppressed reaction to skin tests
- thinning hair

Endocrine and Metabolism:

- 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 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

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
- diarrhea
- indigestion
- bowl/bladder dysfunction
- increased appetite

Hematology:

- Above normal white blood cell count

Hepatic:

- enlarged liver

Musculoskeletal:

- 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)
- pain and inflammation of the tissues surrounding the injection site
- joint pain

Neurologic:

- seizures
- headache
- vertigo
- pain and tenderness
- impaired sensation, strength, and reflexes
- sensation of tingling, tickling, prickling, or burning of a person's skin
- amnesia
- dizziness

Ophthalmologic:

- cataracts
- increased intraocular pressure
- glaucoma
- bulging of the eye
- blindness

Psychiatric:

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

Sexual Function/Reproduction:

- menstrual irregularities
- increased or decreased motility and number of sperm

Other:

- hiccups, fatigue, irritability

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 back passage, black or bloodstained stools and/or vomiting blood			√
Flare up of a previous TB* : 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 are headaches or generally feeling unwell)		√	
Fast/pounding/irregular heartbeat		√	

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	
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		√	

This is not a complete list of side effects. For any unexpected effects while taking DEPO-MEDROL, contact your doctor or pharmacist.

HOW TO STORE IT

Store between 15°C and 30°C. Protect from freezing. Keep out of reach and sight of children.

MGPC Formulations: Store between 20°C to 25°C, excursions permitted between 15°C-30°C. Protect from freezing.

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 0701D
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 can be found at:
<http://www.pfizer.ca>
or by contacting the sponsor, Pfizer Canada Inc., at:
1-800-463-6001.

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