

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

Pr DEPO-MEDROL

Methylprednisolone acetate injectable suspension USP

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

What is DEPO-MEDROL used for?

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

How does DEPO-MEDROL work?

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

What are the ingredients in DEPO-MEDROL?

Medicinal ingredients: Methylprednisolone acetate

Non-medicinal ingredients: DEPO-MEDROL multi-dose: benzyl alcohol, dibasic sodium phosphate, monobasic sodium phosphate, polyethylene glycol 3350, polysorbate 80, and sodium chloride.

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

DEPO-MEDROL comes in the following dosage forms:

1) DEPO-MEDROL with benzyl alcohol:

- 20 mg/mL dose, supplied in 5 mL vials and packaged in cartons of 1.
- 40 mg/mL dose, supplied in 2 mL and 5 mL vials and packaged in cartons of 5.
- 80 mg/mL dose, supplied in 5 mL vials and packaged in cartons of 1.

2) DEPO-MEDROL with myristyl gamma picolinium chloride (MGPC):

- 40 mg/mL dose, supplied in 1 mL vials and packaged in cartons of 10.
- 80 mg/mL dose, supplied in 1 mL vials and packaged in cartons of 5.

Do not use DEPO-MEDROL if:

- you have allergies to methylprednisolone acetate or any other steroid medicine or any of the other ingredients in DEPO-MEDROL
- you have any fungal infection

- you have a blood condition called idiopathic thrombocytopenic purpura if DEPO-MEDROL is given to you through injection into your muscle. This condition is when you have a low blood platelet count.
- you received certain types of vaccines that are live or live-attenuated
- you have viral diseases including cowpox (vaccinia), chicken pox (varicella), and herpes simplex of the eye
- you have unstable joints, when DEPO-MEDROL is injected into the joint.

DEPO-MEDROL should not be injected into your veins or your spine.

DEPO-MEDROL with the preservative, benzyl alcohol should NOT be given to premature infants. However, DEPO-MEDROL with the preservative, myristyl gamma picolinium chloride (MGPC) may be used.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take DEPO-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 DEPO-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;
- 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 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 diseases such as glaucoma, cataracts; herpes infection;
- have kidney disease;
- 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 Cushing's disease (caused by an excess of cortisol hormone)
- have weak immune response. Tell your healthcare professional if you suspect an infection has occurred, as corticosteroids (such as DEPO-MEDROL) can make infections more likely and may mask their signs;
- have diabetes or high blood sugar;
- 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:

DEPO-MEDROL with benzyl alcohol (preservative) is suitable for multidose use. However, multidose use of DEPO-MEDROL is not recommended for intra-synovial injection (injection to the joint).

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

- skin cancer (Kaposi's sarcoma): Kaposi's sarcoma has been reported with corticosteroid therapy, such as DEPO-MEDROL. Stopping treatment of DEPO-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 DEPO-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 health care professional (for example, your doctor, dentist or anesthetist) that you are taking DEPO-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 DEPO-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 DEPO-MEDROL) may get into breast milk.

Male fertility:

Taking DEPO-MEDROL may affect male fertility.

Stopping treatment:

Talk to your healthcare professional before stopping DEPO-MEDROL.

If you suddenly stop taking DEPO-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 DEPO-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 DEPO-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.
- DEPO-MEDROL with the 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.

Driving and Using Machines: DEPO-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 DEPO-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, carbamezipine, phenobarbital, phenytoin and primidone
- treat heartburn and acid indigestion such as cimetidine
- help prevent organ rejection such as cyclosporine or tacrolimus
- treat heart problems or high blood pressure such as calcium channel blockers, digoxin and diltiazem
- reduce extra fluid in the body (water pills {or diuretics)
- for hormone replacement therapy or hormonal oral contraceptives (such as ethinyl estradiol and norethindrone)
- 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
- vaccines – Tell your doctor or nurse if you have recently had, or are about to have any vaccination
- treat diabetes
- treat tuberculosis (such as isoniazid)
- treat high cholesterol such as cholestyramine
- treat breast or ovarian cancer such as aromatase inhibitors

- suppress or reduce the strength of the body's immune system such as immunosuppressants

Do not drink grapefruit juice while taking DEPO-MEDROL.

How to take DEPO-MEDROL:

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 healthcare professional.

The dose of DEPO-MEDROL you get will depend on your condition and how severe it is.

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

Treatment with DEPO-MEDROL should not be stopped suddenly.

Overdose:

If you think you, or a person you are caring for, have taken too much DEPO-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 DEPO-MEDROL?

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

Infections:

DEPO-MEDROL may:

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

Allergic Reactions:

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

Heart Problems:

- heart failure
- heart attack
- arrhythmia (irregular heartbeat)
- high and low blood pressure
- blood clots
- thrombophlebitis (vein inflammation)
- cardiac arrest
- pediatric hypertrophic cardiomyopathy (thickening of heart muscle)
- facial blushing

Skin Problems:

- 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 Problems:

- 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 hypothalamic-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
- lowered carbohydrate (sugar) tolerance
- buildup of acid in the body (metabolic acidosis)
- sodium and fluid retention

Gastrointestinal Problems:

- 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
- bowel/bladder dysfunction

- increased appetite
- peritonitis

Blood Problems:

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

Liver Problems:

- enlarged liver

Musculoskeletal Problems:

- 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
- Osteonecrosis (death of bone tissue)

Nervous System Problems:

- 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
- inflammation of nerves (neuritis)
- nerve damage
- abnormal amount of fat deposit around the spine (epidural lipomatosis)

Eye Problems:

- cataracts
- increased eye pressure
- glaucoma
- bulging of the eye (protrusion of the eyeball)
- blindness
- retinal detachment

Psychiatric Problems:

- 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 Problems:

- irregular periods
- increased or decreased motility and number of sperm

Other Problems:

- hiccups, fatigue, irritability, swelling
- 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

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	
Stomach ulcers (burst or bleeding ulcers): symptoms of which are stomach pain, black or bloodstained stools and/or vomiting blood			√
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: persistent fever/cough/sore throat, painful urination, eye pain/discharge}		√	
High blood pressure: headaches or generally feeling unwell		√	

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	
Fast, pounding or irregular heartbeat		√	
Swelling		√	
Cramps and spasms		√	
Vision changes		√	
Increased thirst or urination		√	
Mental problems: feeling high (mania), mood swings, depression, suicidal thinking, agitation, anxiety, trouble sleeping, confusion, losing your memory		√	
Tendon pain			√
Bone and joint pain			√
Easy bruising and bleeding			√
Pain, redness or 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		√	

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. Protect from freezing. Keep out of reach and sight of children.

For DEPO-MEDROL containing myristyl gamma picolinium chloride (MGPC): Store between 20°C to 25°C. Excursions permitted between 15°C to 30°C. Protect from freezing. Keep out of reach and sight of children.

If you want more information about DEPO-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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