

Patient Medication Information

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PrDEPO-MEDROL WITH LIDOCAINE

methylprednisolone acetate and lidocaine hydrochloride injectable suspension

This patient medication information is written for the person who will be given **DEPO-MEDROL with Lidocaine**. 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 **DEPO-MEDROL with Lidocaine**, talk to a healthcare professional.

What DEPO-MEDROL with Lidocaine is used for:

DEPO-MEDROL with Lidocaine is used as an additional treatment in adults to treat acute or worsening inflammation of joints and tendons.

How DEPO-MEDROL with Lidocaine works:

- DEPO-MEDROL with Lidocaine contains methylprednisolone acetate and lidocaine hydrochloride.
- Methylprednisolone belongs to a group of medicines called corticosteroids hormones. It decreases the body's immune response to certain diseases and reduces inflammation.
- Lidocaine is a local anesthetic. It numbs the area of the body where it is used and reduces pain and inflammation.

The ingredients in DEPO-MEDROL with Lidocaine are:

Medicinal ingredients: methylprednisolone acetate and lidocaine hydrochloride.

Non-medicinal ingredients: benzyl alcohol, myristyl-gamma-picolinium chloride, polyethylene glycol 3350, sodium chloride and water for injection.

DEPO-MEDROL with Lidocaine comes in the following dosage forms:

Suspension: 40 mg/mL methylprednisolone acetate and 10 mg/mL lidocaine hydrochloride.

Do not use DEPO-MEDROL with Lidocaine if:

- you have allergies to:
 - methylprednisolone acetate;
 - any other steroid medicine;
 - lidocaine or any similar local anesthetics;
 - any of the other ingredients in DEPO-MEDROL with Lidocaine.
- you have any fungal infection or any untreated infection;
- you have a blood condition called idiopathic thrombocytopenic purpura if DEPO-MEDROL with Lidocaine is given to you through an injection into your muscle. This is a condition when you have a low blood platelet count;
- you have recently received a type of vaccine called a live or live-attenuated vaccine. Do not receive this vaccine during treatment with DEPO-MEDROL with Lidocaine;

- you have viral diseases including cowpox (vaccinia), chicken pox (varicella), and herpes simplex of the eye;
- you have unstable joints when DEPO-MEDROL with Lidocaine is injected into the joint.

DEPO-MEDROL with Lidocaine should not be injected into your muscles, your veins or your spine.

DEPO-MEDROL with Lidocaine should NOT be given to premature infants because it contains the preservative benzyl alcohol.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you are given DEPO-MEDROL with Lidocaine. 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 any heart problems such as a heart attack, heart failure, heart rate or rhythm disorders or heart disease;
- have a condition where your body has lost fluid (such as blood or water, due to a recent trauma or severe dehydration)
- have bleeding or blood clotting problems;
- have brittle bone disease (osteoporosis);
- have high blood pressure;
- have water retention (edema);
- have epilepsy, seizures or other nervous system problems;
- have thyroid problems;
- have muscle pain or 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 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 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 DEPO-MEDROL with Lidocaine) can make infections more likely and may mask their signs;
- have diabetes or high blood sugar;
- have a condition known as systemic sclerosis, in which your body makes too much of a protein called collagen
- had prior use of DEPO-MEDROL with Lidocaine.

Other warnings you should know about:

DEPO-MEDROL with Lidocaine can cause serious and potentially fatal reactions. Your healthcare professional will give you DEPO-MEDROL with Lidocaine in a medical setting that allows for immediate treatment if serious reactions occur.

DEPO-MEDROL with Lidocaine can cause serious side effects, including:

- **Kaposi's sarcoma** (skin cancer): Kaposi's sarcoma have been reported with corticosteroid therapy, such as DEPO-MEDROL with Lidocaine. Stopping treatment of DEPO-MEDROL with Lidocaine may result in signs of the cancer going away.
- **Pheochromocytoma** (tumour of the adrenal glands): This tumour has been reported with corticosteroid therapy, such as DEPO-MEDROL with Lidocaine. 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 DEPO-MEDROL with Lidocaine.

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 with Lidocaine 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 with Lidocaine) may get into breast milk.

Male fertility:

Taking DEPO-MEDROL with Lidocaine may affect male fertility.

Stopping treatment:

Talk to your healthcare professional before stopping DEPO-MEDROL with Lidocaine.

If you suddenly stop taking DEPO-MEDROL with Lidocaine, 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 are exposed to measles or chickenpox during treatment with DEPO-MEDROL with Lidocaine, contact your healthcare professional immediately. Serious or fatal side effects can

occur if you have not already had these infections or been immunized/vaccinated for these infections previously.

- DEPO-MEDROL with Lidocaine 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 DEPO-MEDROL with Lidocaine since it can affect the results of skin tests.

Driving and using machines:

DEPO-MEDROL with Lidocaine may cause dizziness, vertigo, vision problems, fatigue, temporary mobility and movement problems. 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 with Lidocaine:

Medicines used to:

- treat glaucoma and epilepsy such as acetazolamide
- prevent or treat nausea and vomiting associated with cancer chemotherapy treatment such as aprepitant or fosaprepitant
- treat cancer such as cyclophosphamide
- treat Cushing's syndrome, breast or ovarian cancer (aromatase inhibitors) such as aminoglutethimide
- "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, rifampicin and rifabutin
- treat inflammation such as aspirin and non-steroidal anti-inflammatory medicines (also called NSAIDs) such as ibuprofen
- treat epilepsy such as barbiturates, carbamazepine, phenobarbital, phenytoin and primidone
- treat heartburn and acid indigestion such as cimetidine
- prevent organ rejection such as cyclosporine or tacrolimus
- treat heart problems or high blood pressure such as digoxin and diltiazem
- reduce extra fluid in the body (diuretics, also known as "water pills")
- hormone replacement therapy or hormonal oral contraceptives such as ethinyl estradiol and norethindrone
- treat HIV infections such as indinavir or ritonavir
- to block signals between nerves and muscles in surgery (neuromuscular blocking agents) such as pancuronium or vecuronium

- vaccines. Tell your healthcare professional if you have recently had, or are about to have any vaccinations.
- treat diabetes
- treat tuberculosis such as isoniazid
- treat high cholesterol such as cholestyramine
- treat pain and inflammation such as other local anesthetics
- treat heart rhythm disorders or irregular heartbeat

Do not eat grapefruit or drink grapefruit juice while taking DEPO-MEDROL with Lidocaine.

How DEPO-MEDROL with Lidocaine is given:

- DEPO-MEDROL with Lidocaine will be given to you by your healthcare professional. It will be given as an injection into the joint or the tendon (intra-articular, intrasynovial, intrabursal or periarticular).
- 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.
- Your 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 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 DEPO-MEDROL with Lidocaine, 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 DEPO-MEDROL with Lidocaine:

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

Side effects of DEPO-MEDROL with Lidocaine may include:

- facial blushing;
- skin problems such as reddish spots containing blood that appear in your skin, red or tender bumps on your skin, acne, 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.

DEPO-MEDROL with Lidocaine 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	
Unknown			
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 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.			✓

Frequency/Side Effect/Symptom	Talk to your healthcare professional		Stop taking this drug and get immediate medical help
	Only if severe	In all cases	
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.			√
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 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,		√	

Frequency/Side Effect/Symptom	Talk to your healthcare professional		Stop taking this drug and get immediate medical help
	Only if severe	In all cases	
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.			√
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):			√

Frequency/Side Effect/Symptom	Talk to your healthcare professional		Stop taking this drug and get immediate medical help
	Only if severe	In all cases	
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.			✓
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.			✓

Frequency/Side Effect/Symptom	Talk to your healthcare professional		Stop taking this drug and get immediate medical help
	Only if severe	In all cases	
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 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			√

Frequency/Side Effect/Symptom	Talk to your healthcare professional		Stop taking this drug and get immediate medical help
	Only if severe	In all cases	
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:

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

If you want more information about DEPO-MEDROL with Lidocaine:

- 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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