

## **PATIENT MEDICATION INFORMATION**

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

#### **Pr DEPO-MEDROL WITH LIDOCAINE\***

Methylprednisolone acetate and lidocaine hydrochloride injectable suspension

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

#### **What is DEPO-MEDROL with Lidocaine 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 does DEPO-MEDROL with Lidocaine work?**

- DEPO-MEDROL with Lidocaine contains methylprednisolone acetate and lidocaine hydrochloride.
- Methylprednisolone belongs to a group of medicines called corticosteroids hormones. When injected into the body, it decreases the body's immune response to certain diseases. This helps reduce the symptoms caused by inflammation.
- Lidocaine is a local anesthetic. When injected, it numbs a certain area of the body. This helps to reduce pain and inflammation.

#### **What are the ingredients in DEPO-MEDROL with Lidocaine?**

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 or;
  - any other steroid medicine or;
  - lidocaine or any similar local anaesthetics or;
  - any of the other ingredients in DEPO-MEDROL with Lidocaine
- you have any fungal infection; or
- you have a blood condition called idiopathic thrombocytopenic purpura (low platelet count). Do not administer DEPO-MEDROL with Lidocaine intramuscularly; or
- you have received certain types of vaccines (shots) that are live or live-attenuated; or
- you have viral diseases including vaccinia (cow pox), varicella (chicken pox), and herpes simplex of the eye; or
- 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, veins or your spine; or
- be given to premature infants because the formulation contains benzyl alcohol.

**To help avoid side effects and ensure proper use, talk to your healthcare professional before you take 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);
- recently had myocardial infarction (heart attack);
- have a heart conduction problem. This is a problem with the electrical system that controls your heart's rate and rhythm
- have an abnormally slow heartbeat
- have a low blood volume condition (hypovolemia)
- have a thromboembolic disorders (bleeding or blood clotting problems);
- have brittle bones (osteoporosis);
- have high blood pressure;
- have water retention (oedema);
- have epilepsy, seizures (fits);
- have a thyroid problem;
- have muscle pain or weakness (such as myasthenia gravis);
- have heart problems such as heart failure;
- 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 (ulcer, ulcerative colitis);
- have low potassium or calcium;
- have Cushing's disease (caused by an excess of cortisol hormone);
- have a weak immune response;
- have high blood sugar;
- have a condition known as systemic sclerosis, in which your body makes too much of a protein called collagen.

**Other warnings you should know about:**

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

- skin cancer (Kaposi's sarcoma). 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.
- tumor of the adrenal glands (pheochromocytoma). This tumor has been reported with corticosteroid therapy, such as DEPO-MEDROL with Lidocaine. Pheochromocytoma may cause death.

- fat deposition on or outside the lining of the spine (epidural lipomatosis).
- DEPO-MEDROL with Lidocaine can cause serious and potentially fatal reactions. Your Healthcare Professional will administer DEPO-MEDROL with Lidocaine in a facility that allows for immediate treatment

**Immunosuppression:**

- DEPO-MEDROL with Lidocaine may:
  - hide symptoms of infection
  - cause new infections due to lowered body resistance
- Tell your healthcare professional you are taking DEPO-MEDROL with Lidocaine since it can affect the results of skin tests

**Male fertility:** Taking DEPO-MEDROL with Lidocaine may affect male fertility.

**Pregnancy and breastfeeding:**

- If you are pregnant, or still able to get pregnant and/or breastfeed, 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.
- If you are breastfeeding or planning to breastfeed, tell your healthcare professional.

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

**Children (less than 18 years of age):**

- Corticosteroids can affect growth in children.
- DEPO-MEDROL with Lidocaine contains benzyl alcohol. DEPO-MEDROL with Lidocaine is not recommended for use in infants since benzyl alcohol can cause “gasping syndrome”. “Gasping syndrome” may result in death.

**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:**

- 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)
- other local anesthetic drugs
- Class Ib antiarrhythmic drugs

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

**How to take DEPO-MEDROL with Lidocaine:**

- DEPO-MEDROL with Lidocaine is to be given to you as an intrasynovial injection into the joint or the tendon by your healthcare provider.

**Usual dose:**

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

When your condition has improved, your dose will be reduced gradually. DEPO-MEDROL with Lidocaine should not be stopped abruptly.

**Overdose:**

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

Potential side effects with DEPO-MEDROL with Lidocaine include:

**Skin problems:**

- thin fragile skin
- Face oedema (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
- abscess
- suppressed reaction to skin tests

**Heart Problems:**

- facial blushing

**Hormone 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
- hypopituitarism (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
- thinning hair
- increased sweating
- lightening or darkening of area of skin
- acne

**Stomach and intestinal problems:**

- nausea
- vomiting or altered sense of taste (with rapid administration of large doses)
- abdominal pain
- bloating
- diarrhea
- indigestion
- increased appetite

**Musculoskeletal Problems:**

- loss of muscle mass
- muscle pain
- malaise (feeling of general discomfort or uneasiness)
- pain and inflammation of the tissues surrounding the injection site

**Nervous system problems:**

- headache
- vertigo
- pain and tenderness
- impaired sensation, strength, and reflexes
- sensation of tingling, tickling, prickling, or burning of a person's skin
- sensation of heat, cold, numbness
- twitching
- light-headedness
- dizziness
- drowsiness
- ringing in the ears
- tremors
- fainting
- amnesia
- tongue numbness

**Psychiatric Problems:**

- emotional instability
- euphoria (intense feelings of well-being, elation, happiness, excitement and joy)
- nervousness
- mood swings
- personality changes
- drug dependence
- mania
- delusion
- schizophrenia
- abnormal behavior
- irritability

**Sexual Function/Reproduction:**

- increased or decreased motility and number of sperm

**Other:**

- injection site reaction
- hiccups
- fatigue

DEPO-MEDROL with Lidocaine can cause abnormal blood test results. Your healthcare professional will do blood tests during your treatment.

<b>Serious side effects and what to do about them</b>			
<b>Symptom / effect</b>	<b>Talk to your healthcare professional</b>		<b>Stop taking drug and get immediate medical help</b>
	<b>Only if severe</b>	<b>In all cases</b>	
Coma			√
Breathing problems or breathing stops			√
Stomach ulcers (Burst or bleeding ulcers): stomach pain, bleeding from the back passage, black or bloodstained stools and/or vomiting blood			√
Flare up of a previous tuberculosis: coughing blood or pain in the chest			√
Serious allergic reaction: rash, hives, swelling of the face, lips, tongue or throat. Difficulty swallowing or breathing			√
Infection: persistent fever/cough/sore throat, painful urination, eye pain/discharge		√	
High blood pressure: headaches or generally feeling unwell		√	
bowel/bladder dysfunction: not reaching the bathroom in time, having to pee multiple times during the night		√	
peritonitis (swelling of the stomach lining): severe belly pain that is worse when you move, feeling sick to your stomach or throwing up, fever, swollen belly		√	
pathological fractures (broken bones): pain, bruising and swelling over the broken bone		√	
vertebral compression fractures: sudden back pain that is worse when walking or standing		√	
tendon rupture (break), (particularly of the Achilles tendon): a snap or popping sound with severe pain at the site of the		√	

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	
break, bruising, inability to use the arm or leg with the break			
Charcot joint disease: joint swelling or pain, heat or redness over the joint		√	
inflammation of the pancreas and esophagus: severe belly pain, feeling sick to the stomach, throwing up; hard or painful swallowing, chest pain, heartburn			√
perforation of the bowel: belly pain, feeling bloated, feeling sick to the stomach or throwing up			√
Pancreatitis (inflammation of the pancreas): upper abdominal pain, fever, rapid heart beat, nausea, vomiting, tenderness when touching the abdomen		√	
Liver enlargement: jaundice (yellowing of the skin or whites of eyes), urine turns dark, nausea, vomiting, lower stomach pain		√	
Blood clots: swelling, pain or tenderness, usually in the arm or leg		√	
Heart failure: Shortness of breath, fatigue, weakness, dizziness, irregular heart beat			√
Osteoporosis (thin, fragile bones) bone/joint pain, broken bones, back pain that gets worse when standing or walking			√
Convulsions			√
Irregular menstrual periods	√		
Muscle weakness			√
Fluid retention, swelling		√	
Cramps and spasms		√	
Visual problems: failing eyesight, double vision, blurry vision, eye pain, increased pressure in your eyes		√	
Diabetes: Increased thirst/urination		√	



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	
Psychological disorders: feeling depressed including thinking about suicide, feeling anxious, insomnia		√	
Tendon pain			√
Easy bruising/bleeding			√
Thinning skin	√		
Wounds that are slow to heal	√		
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.

#### 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 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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