

**Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986**

This medicine is dispensed with a doctor's prescription only

## Depo-Medrol® with Lidocaine Suspension for injection



Each 1 ml of solution for injection contains: methylprednisolone acetate 40 mg lidocaine (as hydrochloride) 10 mg

Inactive ingredients and allergens: See section 2 under 'Important information about some of this medicine's ingredients' and section 6 'Further information'.

**Read the entire leaflet carefully before using this medicine.** This leaflet contains concise information about this medicine. If you have any further questions, consult your doctor, pharmacist, or nurse. This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar to yours.

### 1. WHAT IS THIS MEDICINE INTENDED FOR?

For short-term adjunctive therapy (during acute episodes or exacerbation) in the following conditions:

- synovitis or osteoarthritis
- rheumatoid arthritis
- acute and subacute bursitis
- acute gouty arthritis
- epicondylitis
- acute nonspecific tenosynovitis
- post-traumatic osteoarthritis.

**Therapeutic group:** injectable corticosteroids and local anaesthetic.

Corticosteroids are produced naturally in the body and are important for many body functions.

The local anaesthetic helps to reduce local pain caused by injecting this medicine.

**The medicine is intended for** intra-articular, intrasynovial, intrabursal, into the cyst and tendon sheath administration only.

### 2. BEFORE USING THIS MEDICINE

**Do not use this medicine:**

- If you think you have ever suffered from an **allergic** reaction, or any other reaction after receiving Depo-Medrol® with Lidocaine or any other medicine containing a corticosteroid, a local anaesthetic, or any of the other ingredients in this medicine (see section 6). An allergic reaction may cause a skin rash or redness, swelling of the face or lips or shortness of breath.
- If you get a **rash**, or another symptom of an infection.
- If you have recently had, or are about to have any **vaccination**.
- In neonates or premature babies.

**Contact your doctor immediately if one or more of the above applies to you.**

**Do not inject this medicine:**

- into the **Achilles tendon** (which is located behind the ankle joint).

- directly into a **vein (intravenous)**, into the spinal cord (intrathecal), into the nostrils (intranasal), in the eye (intraocular).

**Special warnings regarding use of the medicine Before treatment with Depo-Medrol® with Lidocaine, tell your doctor if any of the following conditions apply to you:**

- **Acute adrenal insufficiency** (when the body cannot produce enough corticosteroid due to problems with the adrenal glands).
- **Acute pancreatitis** (inflammation of the pancreas).
- **Chickenpox, measles, shingles or herpes** in the eye. If you think you have been in contact with someone who has chickenpox, measles or herpes zoster and you have not already had these illnesses in the past, or if you are unsure whether you have had these illnesses in the past.
- Severe **depression** or **manic depression** (bipolar disorder).

This includes having had depression before while taking steroid medicines like Depo-Medrol® with Lidocaine, or having a family history of these illnesses.

- **Cushing's disease** (a condition caused by an excess of cortisol hormone in the body).
- **Diabetes** (or if there is a family history of diabetes).
- **Epilepsy, fits or seizures.**
- **Glaucoma** (increased pressure in the eye) or if there is a family history of glaucoma.
- You experience **blurred vision or other visual disturbances.**

- You have recently suffered from a **heart attack.**
- **Heart problems**, including heart failure or infections.
- **Hypertension** (high blood pressure).
- **Hypotension** (low blood pressure).
- **Hypothyroidism** (an under-active thyroid).
- **Joint infection** which is active and so requires treatment.

- **Kidney or liver disease.**
- **Scleroderma** (also known as systemic sclerosis, an autoimmune disorder), because the risk of a serious complication called scleroderma renal crisis due to scleroderma may be increased. Signs of scleroderma renal crisis include increased blood pressure and decreased urine production.
- **Muscle problems** (pain or weakness) which happened while taking steroid medicines in the past.
- **Myasthenia gravis** (a condition causing tired and weak muscles).

- If you have recently had an **operation.**
- **Osteoporosis** (brittle bones).
- **Peritonitis** (inflammation of the thin lining (peritoneum) around the gut and stomach).
- **Pheochromocytoma** (a rare tumor of adrenal gland tissue. The adrenal glands are located above the kidneys).
- **Skin abscess** or other disorders of the skin.
- **Stomach ulcer** or other serious gastric or intestinal problems (ulcerative colitis).
- Unusual **stress.**
- **Thrombophlebitis** - vein problems due to thrombosis (blood clots in the veins) resulting in phlebitis (red, swollen and tender veins).
- You have **tuberculosis** or have suffered tuberculosis in the past.
- **Traumatic brain injury.**

**You must notify** your doctor or nurse before using this medicine if any of the conditions listed above applies to you.

Your doctor may have to monitor the treatment more

carefully, change the dosage or give you another medicine.

**Mental problems during treatment with Depo-Medrol® with Lidocaine**

Mental health problems can happen while taking steroids like Depo-Medrol® with Lidocaine (see section 4, Side effects).

- These illnesses can be serious.
- They usually start within a few days or weeks of starting treatment with the medicine.
- They are more likely to happen at high doses.
- Most of these problems go away if the dose is lowered or the medicine is stopped. However, if the problems do happen they might need treatment.

Inform your doctor if you (or someone else using this medicine) show any signs of mental problems. This is particularly important if you are depressed, or might be thinking about suicide. In a few cases, mental problems have happened when doses are being lowered or stopped.

Please consult your doctor if you have further questions about using this medicine.

#### Children

Corticosteroids can affect growth in children (see section 3).

#### Tests and follow up

**If you require a test to be carried out by a doctor or in a hospital,** it is important that you tell the doctor or nurse that you are treated with Depo-Medrol® with Lidocaine. This medicine can affect the results of some tests.

#### Drug interactions

**If you are taking or have recently taken other medicines, including nonprescription medicines and dietary supplements, tell your doctor or pharmacist.** Particularly if you are taking:

- **Acetazolamide** – a medicine used to treat glaucoma and epilepsy.
- **Aminoglutethimide and cyclophosphamide** – medicines used to treat cancer.
- **Antibacterials** (such as isoniazid, erythromycin, clarithromycin and troleandomycin).
- **Antivirals** (such as ritonavir, indinavir) and **pharmacokinetic enhancers** (such as cobicistat) used to treat HIV infection (AIDS).
- **Anticoagulants** - medicines used for blood "thinning" such as acenocoumarol, phenindione and warfarin.
- **Anticholinesterases** - medicines used to treat myasthenia gravis (severe muscle weakness) such as distigmine and neostigmine.
- **Antidiabetics** – medicines used to treat high blood sugar.
- **Antiemetics** (such as aprepitant and fosaprepitant).
- **Aspirin and non-steroidal anti-inflammatory drugs** (also called NSAIDs) such as ibuprofen used to treat mild to moderate pain.
- **Barbiturates, carbamazepine, phenytoin and primidone** – medicines used to treat epilepsy.
- **Carbenoxolone** - used for heartburn and acid indigestion.
- **Ciclosporin** - a medicine used to treat conditions such as severe rheumatoid arthritis or severe psoriasis, or given following an organ or bone marrow transplant.

- **Digoxin** - a medicine used to treat heart failure and/or irregular heart beat.

- **Diltiazem** – a medicine used to treat heart problems or high blood pressure.

- **Ethinylestradiol and norethindrone** – oral contraceptives.

- **Ketoconazole or itraconazole** – medicines used to treat fungal infections.

- **Pancuronium and vecuronium** – or other medicines called neuromuscular blocking agents which are used in certain surgical procedures.

- Potassium depleting medicines – such as **diuretics, amphotericin B, xanthenes or beta 2 agonists** (e.g. medicines used to treat asthma).
- **Rifampicin and rifabutin** – antibiotics used to treat tuberculosis.

- **Tacrolimus** – a medicine given following an organ transplantation to prevent rejection of the transplanted organ.
- **Vaccines** - Tell your doctor or nurse if you have recently had, or are about to have any vaccination. You **must not** receive any "live attenuated" vaccine while using this medicine. Other vaccines may be less effective.

**If you are taking regular medicines** If you are taking medicines for treatment of diabetes, high blood pressure or water retention (edema) tell your doctor, as he may need to adjust the dosage of the medicines used to treat these conditions.

**Before you have any operation** tell your doctor, dentist or anesthesiologist that you are taking Depo-Medrol® with Lidocaine.

#### Using this medicine and food

Do not drink grapefruit juice while being treated with Depo-Medrol® with Lidocaine.

#### Pregnancy, breastfeeding and fertility

If you are pregnant, think you may be pregnant or are planning to become pregnant, ask your doctor for advice before taking this medicine, as this medicine can slow the baby's growth. There is a risk associated with low birth weight of the baby; this risk can be reduced by using a lower dosage of this medicine.

Cases of cataracts have been observed in infants born to mothers treated with long-term corticosteroids during pregnancy.

If you are breastfeeding, ask your doctor for advice before taking this medicine, since lidocaine as well as small amounts of corticosteroid medicines are excreted into breast milk.

If you continue breastfeeding during the treatment, your baby will need additional tests to make sure that he is not being affected by your medicine.

#### Driving and using machines

Do not drive or operate dangerous machines while using this medicine if you experience undesirable effects, such as dizziness, vertigo, visual disturbances and fatigue, which are possible after treatment with corticosteroids.

#### Important information about some of this medicine's ingredients

Depo-Medrol® with Lidocaine contains benzyl alcohol and sodium (see section 6).

**Depo-Medrol®** with Lidocaine contains 8.7 mg and 17.4 mg of benzyl alcohol in each 1 ml and 2 ml of solution respectively, which is equivalent to 8.7 mg/ml of benzyl alcohol. Benzyl alcohol may cause allergic reactions. Benzyl alcohol has been linked with the risk of severe side effects including breathing problems (called "gasping syndrome") in young children. Do not use medicines containing benzyl alcohol in newborn babies (up to 4 weeks old), and do not use these medicines for more than

a week in young children (less than 3 years old), unless explicitly determined as necessary by the doctor. Tell your doctor or pharmacist if you have liver or kidney problems or if you are pregnant or breastfeeding. This is because large amounts of benzyl alcohol may build-up in the body and may cause side effects such as an increased amount of acid in your blood (called "metabolic acidosis"). Depo-Medrol® with Lidocaine contains less than 1 mmol sodium (23 mcg) per vial, that is to say essentially 'sodium-free'.

### 3. HOW TO USE THIS MEDICINE?

Always use this preparation according to your doctor's instructions.

Check with the doctor or pharmacist if you are uncertain about the dosage and treatment regimen of the preparation.

If you are admitted to the hospital for any reason, always tell your doctor or nurse that you are using this medicine. You can also wear a bracelet or pendant (medical identification tag) to let the medical staff know that you are treated with a steroid medicine in case you are involved in an accident or become unconscious.

The dosage and treatment regimen will be determined by your doctor only. The recommended dosage will be adjusted to the medical condition, and the site and mode of administration.

Your doctor will decide on the site of injection, how much of the medicine and how many injections you will receive, depending on the condition you are being treated for and its degree of severity. Your doctor will inject you the lowest dose for the shortest possible time to get effective relief of your symptoms.

#### Adults

Your doctor or nurse will tell you how many injections you will require for the condition you are being treated for, and when you will receive them.

#### Recommended doses:

##### Joints:

The usual dose for injections into the joint will depend on the size of the joint. Large joints (e.g. knee, ankle and shoulder) may require a dose of 20-80 mg (0.5-2 ml), medium sized joints (e.g. elbow or wrist) a dose of 10-40 mg (0.25-1 ml), and small joints (e.g. finger or toe joints) a dose of 4-10 mg (0.1-0.25 ml). Joint injections may be given once weekly over a period of several weeks, depending on how quickly you respond to treatment.

Bursitis, tenosynovitis, and epicondylitis: The usual dose is between 4-30 mg (0.1-0.75 ml). In most cases repeat injections will not be needed for bursitis and epicondylitis. Repeat injections may be necessary to treat long standing conditions.

#### Elderly

Treatment will normally be the same as for adults. However, your doctor may want to see you more often to check how the medicine affects you.

#### Children

Your doctor will prescribe the lowest dose that will be effective for your child.

#### Do not exceed the recommended dose.

**If you have accidentally received a higher dosage** If you think you have received more injections than you should have received, contact your doctor immediately.

If a child has accidentally swallowed some medicine, immediately see a doctor or go to a hospital emergency room and bring the medicine package with you.

Adhere to the treatment as recommended by your doctor.

Even if your health improves, do not stop treatment with this medicine without consulting your doctor.

**Stopping/reducing the dosage of Depo-Medrol® with Lidocaine**

Your doctor will decide when to stop the treatment. You have to stop the treatment gradually if:

- you have received more than 6 mg (0.15 ml) Depo-Medrol® with Lidocaine for more than 3 weeks;
- you have received a high dosage of Depo-Medrol® with Lidocaine, over 32 mg (0.8 ml) daily, even if it was administered only for 3 weeks or less;
- you have already received a course of corticosteroid tablets or injections in the last year;
- you have already had problems with adrenal glands (adrenocortical insufficiency) before starting the treatment.

You have to stop the treatment gradually to avoid **withdrawal symptoms**. These symptoms may include itchy skin, fever, muscle and joint pains, runny nose, sticky eyes, sweating and weight loss. If the symptoms seem to return or get worse when the medicine's dosage is reduced, contact your doctor immediately.

**Do not take medicines in the dark! Check the label and dose each time you take a medicine. Wear glasses if you need them.**

**If you have any further questions about using this medicine, consult your doctor, pharmacist or nurse.**

### 4. SIDE EFFECTS

As with any medicine, use of Depo-Medrol® with Lidocaine may cause side effects in some users. Do not be alarmed by this list of side effects; you may not experience any of them.

Your doctor has prescribed this medicine for you to treat your condition, which may worsen if not treated properly.

**In certain medical conditions, medicines like Depo-Medrol® with Lidocaine (steroids) should not be stopped abruptly. If you suffer from one or more of the following symptoms, contact your doctor immediately. Your doctor will decide whether you should continue receiving treatment with Depo-Medrol® with Lidocaine.**

- **Allergic reactions**, such as skin rash, swelling of the face or wheezing and difficulty breathing or dizziness. This type of side effect is rare, but may be severe.
- **Pancreatitis** (inflammation of the pancreas), abdominal pain which may spread through to your back, possibly accompanied by vomiting, shock, and loss of consciousness.
- **Burst or bleeding ulcers**, symptoms of which are severe abdominal pain which may go through to the back and could be associated with bleeding from the back passage, black or bloodstained stools and/or vomiting blood.

**Infections**, this medicine can hide or change the signs and symptoms of certain infections, or reduce your resistance to infection, so that they are hard to diagnose at an early stage. Symptoms may include raised temperature and feeling unwell.

Symptoms of a flare up of a previous tuberculosis infection can be coughing up blood or chest pain. In addition, this medicine may make you more likely to develop a severe infection.

- **Peritonitis**, an inflammation (irritation) of the peritoneum, the thin tissue that lines the inner wall of the abdominal cavity and covers most of the abdominal organs. The symptoms are severe abdominal pain or tenderness, the pain may worsen upon touching the abdomen or during body movement.

- **Pulmonary embolism** (a blood clot in the lung), the symptoms include sudden sharp chest pain, breathlessness and coughing up blood.

- **Raised pressure within the skull** of children (pseudotumor cerebri), symptoms of which are headaches with vomiting, lack of energy and drowsiness. This side effect usually occurs after the treatment is stopped.

- **Thrombophlebitis** (blood clots or thrombosis in a leg vein), symptoms of which include painful swollen, red and tender veins.

**If you experience any of the following side effects, or if you experience any unusual effects not mentioned in this leaflet, contact your doctor immediately.**

The following side effects may occur at unknown frequency (the frequency of these effects has not been established yet):

#### Heart and blood vessels

- High blood pressure, symptoms of which are headaches or generally feeling unwell.
- Slowing heart rate (bradycardia).
- Problems with the pumping of your heart (heart failure), symptoms of which are swollen ankles, difficulty in breathing and palpitations (awareness of heartbeats) or irregular beating of the heart, irregular or very fast or slow pulse, cardiac arrest.
- Low blood pressure, the symptoms may include dizziness, fainting, lightheadedness, blurred vision, a rapid or irregular heartbeat (palpitations).
- Increase in white blood cells (leukocytosis).
- Increased clotting of the blood.

#### Balance of water and salts in the body

- Swelling and high blood pressure caused by increased levels of water and salt in the body.
- Cramps and spasms due to loss of potassium from the body. In rare cases this can lead to congestive heart failure (when the heart cannot pump properly).

#### Digestive system

- Ulcers.
- Vomiting.
- Nausea.
- Thrush in the gullet (discomfort on swallowing).
- Indigestion.
- Diarrhea.
- Bloating stomach.
- Abdominal pain.
- Hiccups.

#### Ears

- A feeling of dizziness or spinning (vertigo).

#### Eyes

- Glaucoma (raised pressure within the eye, causing pain in the eyes and headaches).
- Cataract (indicated by failing eyesight).
- Swollen optic nerve (causing a condition called papilledema), and which may cause vision disturbances).

- Increased intraocular pressure with possible damage to the optic nerve (associated with reduced vision).
- Thinning of the clear part at the front of the eye (cornea) or of the white part of the eye (sclera).
- Worsening of viral or fungal eye infections.
- Protrusion of the eyeballs (exophthalmos).
- Blindness, blurred or double vision.
- Blurred or distorted vision (due to disease of the retina and choroid membrane).

#### Hepatobiliary disorders

- Methylprednisolone can damage the liver; cases of hepatitis and increased liver enzymes have been reported.

#### General disorders

- Poor wound healing.
  - Irritability.
  - Feeling tired or unwell.
  - Skin reactions at the site of injection.
- #### Hormones and metabolic system
- Slowing of normal growth in infants, children and adolescents which may be permanent.
  - Round or moon-shaped face (Cushingoid face).
  - Diabetes or worsening of existing diabetes.
  - Irregular or no periods in women.
  - Increased appetite and weight gain.
  - Abnormal localized or tumor-like accumulations of fat in the tissues.
  - Prolonged therapy can lead to low levels of certain hormones, which can cause low blood pressure and dizziness. This effect may persist for months.
  - The amount of certain enzymes (ALT, AST, ALP) that help the body digest medicines and other substances may be raised after treatment with a corticosteroid. The change is usually small and the enzyme levels return to normal after the medicine is cleared naturally from the body. You will not notice any symptoms, but if this happens, it will show up in a blood test.

**If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.**

You can report side effects to the Ministry of Health by following the link 'Reporting Side Effects of Drug Treatment' on the Ministry of Health home page ([www.health.gov.il](http://www.health.gov.il)) which links to an online form for reporting side effects or by using the link: <https://sideeffects.health.gov.il>

- Feeling, seeing or hearing things which do not exist. Having strange and frightening thoughts, changing how you act or having feelings of being alone.

- Other nervous system side effects may include convulsions (seizures), amnesia (loss of memory), cognitive disorders (mental changes), tremor, dizziness and headache, drowsiness, difficulty breathing, sensation of cold, heat or numbness, tinnitus or unconsciousness.

- Back pain or weakness (due to Epidural Lipomatosis, a rare disorder in which an abnormal amount of fat is deposited on or outside the lining of the spine)

#### Skin

- Acne.
- Bruising.
- Abscess, especially near injection sites.
- Thinning of skin, stretch marks.
- Small purple/red patches on the skin.
- Pale or darker patches on the skin, or raised patches of unusual color.
- Increased hair on the body and face (hirsutism).
- Rash, skin redness, itching, hives.
- Increased sweating.

**If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.**

You can report side effects to the Ministry of Health by following the link 'Reporting Side Effects of Drug Treatment' on the Ministry of Health home page ([www.health.gov.il](http://www.health.gov.il)) which links to an online form for reporting side effects or by using the link: <https://sideeffects.health.gov.il>

### 5. HOW TO STORE THE MEDICINE?

- Prevent poisoning! This and any other medicine should be kept in a closed place, out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by a doctor.

- Do not use the medicine after the expiry date (exp. date) which is stated on the package. The expiry date refers to the last day of that month.

- Store below 25°C. Do not freeze.

### 6. FURTHER INFORMATION

**In addition to the active ingredient, this medicine also contains:**

macrogol 3350, benzyl alcohol (E1519), sodium chloride, myristyl-gamma-picolinium chloride, sodium hydroxide, hydrochloric acid, water for injection. In addition, each 1 ml contains 8.7 mg benzyl alcohol and sodium chloride (see section 2).

**What the medicine looks like and contents of the pack:**

A glass vial containing 2 ml of white suspension in a carton pack.

**Registration holder and address:** Pfizer PFE Pharmaceuticals Israel Ltd., 9 Shenkar St., Herzliya Pituach 46725

Registration number of the medicine in the National Drug Registry of the Ministry of Health: 045-97-23829.

Revised in 02/2022 according to MOH guidelines.