Package leaflet: Information for the patient

Depo-Medrone 40 mg/ml with Lidocaine 10 mg/ml, Suspension for Injection
methylprednisolone acetate and lidocaine hydrochloride monohydrate

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- **Depo-Medrone with Lidocaine is a steroid medicine**, prescribed for many different conditions, including serious illnesses.
- **You need to take it regularly** to get the maximum benefit.
- **Don't stop taking this medicine** without talking to your doctor – you may need to reduce the dose gradually.
- **Depo-Medrone with Lidocaine can cause side effects in some people** (see section 4). Some problems such as mood changes (feeling depressed, or "high"), or stomach problems can happen straight away. If you feel unwell in any way, keep taking Depo-Medrone with Lidocaine, but **see your doctor straight away.**
- **Some side effects only happen after weeks or months**. These include weakness of arms and legs, or developing a round face (see section 4 for more information).
- **If you take it for more than 3 weeks, you will get a blue "steroid card".** Always keep it with you and show it to any doctor or nurse treating you.
- **Keep away from people who have chickenpox or shingles,** if you have never had them. They could affect you severely. If you do come into contact with chickenpox or shingles, **see your doctor straight away.**

Read all of this leaflet carefully. It includes other important information on the safe and effective use of this medicine that might be especially important for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Depo-Medrone with Lidocaine is and what it is used for

Depo-Medrone with Lidocaine contains methylprednisolone acetate and lidocaine hydrochloride monohydrate.
Depo-Medrone with Lidocaine belongs to a group of medicines called steroids. Their full name is corticosteroids. These corticosteroids are produced naturally in the body, and help to maintain health and well-being. Boosting your body with extra corticosteroid (such as Depo-Medrone with Lidocaine) is an effective way to treat various illnesses involving inflammation of the body. Depo-Medrone with Lidocaine reduces this inflammation, which could otherwise go on making your condition worse. You must take this medicine regularly to get maximum benefit from it.

When injected into the body, such as in or near a joint, corticosteroids help reduce symptoms caused by inflammatory or rheumatic conditions.

This medicine also contains lidocaine which is a local anaesthetic. Lidocaine helps to reduce any local pain caused by injecting this medicine.

This medicine will be injected by a doctor or nurse to help treat the symptoms caused by the following conditions:

- **Bursitis**: inflammation in the fluid containing spaces around the shoulder, knee and/or elbow joints. For this condition this medicine will be injected directly into one or more of these spaces.
- **Osteoarthritis and rheumatoid arthritis**: inflammation located in between the joints. For these conditions this medicine will be injected directly into one or more joint spaces.
- **Epicondylitis and tenosynovitis:** tennis elbow (epicondylitis), and/or a tendon's covering sheath (tenosynovitis). For these conditions this medicine will be injected into the tendon or its tendon sheath.

Your doctor may use this medicine to treat conditions other than those listed above. You must talk to a doctor if you do not feel better or if you feel worse.

2. What you need to know before you use Depo-Medrone with Lidocaine

Do not use Depo-Medrone with Lidocaine:

- If you think you have ever suffered an **allergic reaction** after being given Depo-Medrone with Lidocaine, or any other medicine containing a corticosteroid or local anaesthetic, or any of the ingredients in this medicine (listed in section 6). An allergic reaction may cause a skin rash or reddening, swollen face or lips or shortness of breath.
- If you get a **rash**, or another symptom of an infection that is not being treated with antibiotics or anti-virals, or if you have a widespread (systemic) fungal infection.
- If you have been told by your doctor you have a condition called **heart block**.
- If you are about to be given a **'live**' vaccine, such as measles or polio vaccines.

See your doctor immediately if any of the above applies to you.

This medicine should not be injected:

- into the **Achilles tendon** (which is located behind the ankle joint)
- directly into a **vein (intravenous),** a **muscle (intramuscular)**, the spinal cord (intrathecal), into the nostrils (intranasal), into the eye (intraocular) or by the epidural route.

Warnings and precautions

Talk to your doctor or nurse before taking Depo-Medrone with Lidocaine if you have any of the following conditions. Your doctor may also have to monitor your treatment more closely, alter your dose or give you another medicine.

- **Acute adrenal insufficiency** (when your body cannot produce enough corticosteroid due to problems with your adrenal glands).
- **Acute pancreatitis** (inflammation of the pancreas).
- **Chickenpox, measles, shingles** or a **herpes** eye infection. If you think you have been in contact with someone with chickenpox, measles or shingles and you have not already had these illnesses, or if you are unsure if you have had them.
- **If you have ever had severe depression** or manic depression (bipolar disorder). This includes having depression before taking steroid medicines like Depo-Medrone with Lidocaine or **if any of your close family** has had these illnesses.
- **Cushing's syndrome** (a hormone disorder caused by high levels of cortisol in the blood).
- **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.
- Contact your doctor if you experience **blurred vision or other visual disturbances**.
- You have recently suffered 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.
- **Karposi's sarcoma** (a type of skin cancer).
- **Kidney or liver disease**.
- **Muscle problems** (pain or weakness) that have happened while taking steroid medicines in the past.
- **Myasthenia gravis** (a condition causing tired and weak muscles).
- **Osteoporosis** (brittle bones, bones that break easily).
- **Pheochromocytoma** (a rare tumour of adrenal gland tissue. The adrenal glands are located above the kidneys).
- **Scleroderma** (also known as systemic sclerosis, an autoimmune disorder) because the risk of a serious complication called scleroderma renal crisis may be increased.
- **Skin abscess** or other disorders of the skin.
- **Stomach ulcer, diverticulitis** (inflammation of the bowel wall) or other serious stomach or intestinal problems (ulcerative colitis).
- Unusual **stress**.
- **Thrombophlebitis**, vein problems due to thrombosis (clots in the veins) resulting in phlebitis (red, swollen and tender veins).
- **Tuberculosis** (TB) or if you have suffered tuberculosis in the past.
- **Traumatic brain injury**.

Other medicines and Depo-Medrone with Lidocaine
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

You should tell your doctor if you are taking any of the following medicines which can affect the way Depo-Medrone with Lidocaine or the other medicine works:
- **Acetazolamide** – used to treat glaucoma and epilepsy.
- **Aminoglutethimide** and **cyclophosphamide** – used for treating cancer.
- **Anaesthetics, local** (medicines used for pain relief in a specific area) – toxic effects are enhanced.
- **Antiarrhythmics** (class Ib- medicines used to control abnormal heart rate) – increased risk of toxicity.
- **Antibacterials** (such as isoniazid, erythromycin, clarithromycin and troleandomycin).
- **Anticoagulants** – used to 'thin' the blood such as acenocoumarol, phenindione and warfarin.
- **Anticholinesterases** – used to treat myasthenia gravis (a muscle condition) 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 medicines (also called NSAIDs) such as ibuprofen used to treat mild to moderate pain.
- **Barbiturates**, **carbamazepine, phenytoin** and **primidone** – used to treat epilepsy.
- **Carbenoxolone** – used for heartburn.
- **Ciclosporin** – used to treat conditions such as severe rheumatoid arthritis, severe psoriasis or following an organ or bone marrow transplant.

- **Digoxin** – used for heart failure and/or an irregular heartbeat.
- **Diltiazem** – used for heart problems or high blood pressure.
- **Ethinylestradiol** and **norethindrone** – oral contraceptives.
- **Indinavir** and **ritonavir** – used to treat HIV infections.
- **Ketoconazole** or **itraconazole** – used to treat fungal infections.
- **Pancuronium** or **vecuronium** – or other medicines called neuromuscular blocking agents which are used in some surgical procedures.
- **Pharmacokinetic enhancers** (such as cobicistat) used to treat HIV infections.
  Potassium depleting agents – such as **diuretics** (sometimes called water tablets), **amphotericin B, xanthenes or beta2 agonists** (e.g. medicines used to treat asthma).
- **Rifampicin** and **rifabutin** – antibiotics used to treat tuberculosis (TB).
- **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. You **must not** have 'live' vaccines while using this medicine. Other vaccines may be less effective.

If you are taking long term medication(s)
If you are being treated for diabetes, high blood pressure or water retention (oedema) tell your doctor as he/she may need to adjust the dose of the medicines used to treat these conditions.

Before you have any operation, tell your doctor, dentist or anaesthetist that you are taking this medicine.

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

Depo-Medrone with Lidocaine with drink
Do not drink grapefruit juice while taking this medicine.

Pregnancy and breast-feeding
If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine, as this medicine could slow the baby's growth.

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

Depo-Medrone with Lidocaine contains benzyl alcohol (see section 2 "Depo-Medrone with Lidocaine contains benzyl alcohol and sodium").

Depo-Medrone with Lidocaine should be used during pregnancy only if clearly needed.

If you are breast-feeding, ask your doctor or pharmacist for advice before taking this medicine, as small amounts of corticosteroid medicines may get into breast milk.

If you continue breast-feeding while you are having treatment, your baby will need extra checks to make sure he or she is not being affected by your medicine.

Depo-Medrone with Lidocaine contains benzyl alcohol (see section 2 "Depo-Medrone with Lidocaine contains benzyl alcohol and sodium").

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

Undesirable effects, such as dizziness, vertigo, visual disturbances and fatigue are possible after treatment with corticosteroids. Temporary mobility and coordination of movement difficulties may also occur due to the anaesthetic effect of lidocaine. If you are affected do not drive or operate machinery.

Depo-Medrone with Lidocaine contains benzyl alcohol and sodium.
Depo-Medrone with Lidocaine contains 17.4 mg of benzyl alcohol in 2 ml of solution, 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 advised by the doctor. Ask your doctor or pharmacist for advice if you have a liver or kidney disease, or if you are pregnant or breast-feeding. This is because large amounts of benzyl alcohol can build-up in your body and may cause side effects such as an increased amount of acid in your blood (called "metabolic acidosis").

Depo-Medrone with Lidocaine contains less than 1 mmol sodium (23 mg) in each vial, that is to say essentially 'sodium-free'.

3. How to use Depo-Medrone with Lidocaine

Steroid Cards
Remember to always carry a Steroid Treatment Card. Make sure your doctor or pharmacist has filled out the details of your medicine, including the dose and how long you will require steroid treatment.

If you are admitted to hospital for any reason always tell your doctor or nurse that you are taking this medicine. You can also wear a medic-alert bracelet or pendant to let medical staff know that you are taking a steroid if you have an accident or become unconscious.

Dosage information
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 being treated and its severity. Your doctor will inject you with the lowest dose for the shortest possible time to get effective relief of your symptoms.

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

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

Bursitis and epicondylitis (tennis elbow) – the usual dose is between 4 to 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 tendonitis but a single injection may also be effective.

Elderly
Treatment will normally be the same as for younger adults. However your doctor may want to see you more regularly to check how you are getting on with this medicine.

Use in children
Corticosteroids can affect growth in children so your doctor will prescribe the lowest dose that will be effective for your child.

If you are given more Depo-Medrone with Lidocaine than you should
If you think you have been given too many injections of this medicine please speak to your doctor immediately.

If you have received too much of this medicine you may have symptoms such as unusual sensation around the mouth, numbness of the tongue, light-headedness, hearing or visual disturbances, muscle spasms, muscle twitching, seizures, loss of consciousness, difficulty in breathing, low blood pressure, irregular heartbeat or heart attack.

Stopping/reducing the dose of your Depo-Medrone with Lidocaine
Your medicine must not be stopped suddenly. Your doctor will decide when it is time to stop your treatment.
You will need to come off this treatment slowly if you:

- have been given Depo-Medrone with Lidocaine for a long time
- have been given high doses of Depo-Medrone with Lidocaine
- have already had a course of corticosteroid tablets or injections in the last year
- already have problems with your adrenal glands (adrenocortical insufficiency) before you started this treatment.

You will need to come off this medicine slowly to avoid **withdrawal symptoms**. These symptoms may include itchy skin, fever, muscle and joint pains, runny nose, sticky eyes, sweating and weight loss.

If your symptoms seem to return or get worse as your dose of this medicine is reduced tell your doctor immediately.

Mental problems while taking Depo-Medrone with Lidocaine
Mental health problems can happen while taking steroids like Depo-Medrone with Lidocaine (see section 4).

- These illnesses can be serious.
- Usually they start within a few days or weeks of starting 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 problems do happen they might need treatment.

Talk to a doctor if you (or someone **taking** 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.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side-effects, although not everybody gets them.
Your doctor will have given you this medicine for a condition which if not treated properly could become serious.

In certain medical conditions, medicines like Depo-Medrone with Lidocaine (steroids) should not be stopped abruptly. If you suffer from any of the following symptoms seek IMMEDIATE attention. Your doctor will then decide whether you should continue taking your medicine.

- **Allergic reactions**, such as skin rash, swelling of the face or wheezing and difficulty breathing. This type of side effect is rare, but can be serious.
- **Pancreatitis**, stomach pain which may spread through to your back, possibly accompanied by vomiting, shock and loss of consciousness.
- **Ulcers or bleeding ulcers**, symptoms of which are severe stomach 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.
- **Cardiac arrest**, when the heart stops beating due to problems with the heart's electrical system caused by abnormal or irregular rhythms (called arrhythmias).
- **Infections**. This medicine can hide or change the signs and symptoms of some infections, or reduce your resistance to the infection, so that they are hard to diagnose at an early stage. Symptoms might include a raised temperature and feeling unwell. Symptoms of a flare up of a previous TB (tuberculosis) infection could be coughing blood or pain in the chest. This medicine may also 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 abdomen and covers most of the abdominal organs. Symptoms are, the stomach (abdomen) being very painful or tender, the pain may become worse when the stomach is touched or when you move.
- **Pulmonary embolus** (blood clot in the lung) symptoms include sudden sharp chest pain, breathlessness and coughing up blood.
- **Raised pressure within the skull of children** (pseudotumour cerebri) symptoms of which are headaches with vomiting, lack of energy and drowsiness. This side-effect usually occurs after treatment is stopped.
- **Thrombophlebitis** (blood clots or thrombosis in a leg vein), symptoms of which include painful swollen, red and tender veins.
- **Phaeochromocytoma crisis**, a serious condition which can occur in patients with an adrenal gland tumour. Symptoms include very high blood pressure, heart attack, fast or irregular heartbeat, headache, abdominal pain or chest pain.

If you experience any of the following side effects, or if you notice any other unusual effects not listed in this leaflet, tell your doctor immediately.

The side effects may occur with certain frequencies, which are defined as follows:

- *not known*: frequency cannot be estimated from the available data.

Blood, heart and circulation
frequency not known

- High blood pressure (hypertension), 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, abnormal heart rate (cardiac arrhythmias).
- Low blood pressure (hypotension), symptoms may include dizziness, fainting, light-headedness, blurred vision, a rapid or irregular heartbeat (palpitations).
- Increased numbers of white blood cells (leukocytosis).
- Increased clotting of the blood.

Body water and salts
frequency not known

- Swelling and high blood pressure, caused by increased levels of water and salt content.

- Cramps and spasms, due to the loss of potassium from your body. In rare cases this can lead to congestive heart failure (when the heart cannot pump properly).

Digestive system
frequency not known
- Ulcers.
- Vomiting (being sick).
- Nausea (feeling sick).
- Thrush in the gullet (discomfort on swallowing).
- Indigestion.
- Diarrhoea.
- Bloated stomach.
- Abdominal pain.
- Persistent hiccups, especially when high doses are taken.

Respiratory system
frequency not known
- Difficult breathing and shallow breath.

Ears
frequency not known
- A feeling of dizziness or spinning (vertigo).
- Ringing in the ear (tinnitus).

Eyes
frequency not known
- Glaucoma (raised pressure within the eye, causing pain in the eyes and headaches).
- Cataracts (indicated by failing eyesight).
- Swollen optic nerve (causing a condition called papilloedema, which may cause sight disturbance).
- Increased intra-ocular pressure, with possible damage to the optic nerve (indicated by failing eyesight).
- 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.
- Protruding of the eyeballs (exophthalmos).
- Blindness, blurred or double vision.
- Blurred or distorted vision (due to a disease of the retina and choroid membrane called chorioretinopathy).

Hepatobiliary disorders
frequency not known
- Methylprednisolone can damage your liver, hepatitis and increase of liver enzymes have been reported.

General disorders
frequency not known
- Poor wound healing.
- Feeling tired or unwell.
- Skin reactions at the site of injection.
- Feeling hot or cold.

Hormones and metabolic system

frequency not known

- Slowing of normal growth in infants, children and adolescents which may be permanent.
- Round or moon-shaped face (Cushingoid facies).
- Excessive quantity of acid in the blood (metabolic acidosis).
- Diabetes or worsening of existing diabetes.
- Irregular or no periods in women.
- Increased appetite and weight gain.
- Abnormal localized or tumour-like accumulations of fat in the tissues.
- Prolonged therapy can lead to lower levels of some hormones which in turn can cause low blood pressure and dizziness. This effect may persist for months.
- The amount of certain chemicals (enzymes) called alanine transaminase, aspartate transaminase and alkaline phosphatase that help the body digest drugs and other substances in your body may be raised after treatment with a corticosteroid. The change is usually small and the enzyme levels return to normal after your medicine has cleared naturally from your system. You will not notice any symptoms if this happens, but it will show up if you have a blood test.

Immune system

frequency not known

- Increased susceptibility to infections which can hide or change normal reactions to skin tests, such as that for tuberculosis.

Metabolism and nutrition disorders

frequency not known

- Accumulation of fat tissue on localized parts of the body.

Muscles, bones and joints

frequency not known

- Muscle weakness.
- Brittle bones (bones that break easily).
- Broken bones or fractures.
- Muscle wasting.
- Breakdown of bone due to poor circulation of blood, this causes pain in the hip.
- Joint pain.
- Torn muscle tendons causing pain and/or swelling.
- Muscle cramps, spasms or twitching.
- Swollen or painful joints due to infection.

Nerves and mood issues

frequency not known

- Feeling depressed, including thinking about suicide.
- Feeling high (mania) or moods that go up and down.
- Feeling irritated or being easily annoyed.
- Feeling anxious, having problems sleeping, difficulty in thinking or being confused and losing your memory.
- Feeling, seeing or hearing things which do not exist. Having strange and frightening thoughts, changing how you act or having feelings of being alone.

Steroids, including Depo-Medrone with Lidocaine, can cause serious mental health problems. These are common in both adults and children. They can affect about 5 in every 100 people taking medicines like Depo-Medrone with Lidocaine. If you notice any of these problems **talk to a doctor straight away.**

- Other nervous system side effects, which may include seizures, dizziness, drowsiness, difficulty breathing, sensation of cold, heat or numbness, twitching, tremors, tinnitus (a continuous ringing sensation in the ears) 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
frequency not known
- Acne.
- Bruising.
- Abscess, especially near injection sites.
- Thinning of skin, stretch marks.
- Small purple/red patches on the skin.
- Pale or darker patches on your skin, or raised patches which are an unusual colour.
- Skin lesions (skin infections, tumours or injury).
- Increased hair on the body and face (hirsutism).
- Rash, skin redness, itching, hives.
- Increased sweating.
- Oedema (swelling of the skin).
- Face swelling (face oedema).
- Urticaria (an itchy skin rash with a burning sensation).

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance. Website: www.hpra.ie. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Depo-Medrone with Lidocaine

Keep this medicine out of the sight and reach of children.
Do not use this medicine after the expiry date which is stated on the label and carton after EXP. The expiry date refers to the last day of that month.
Do not store above 25°C. Do not freeze.
Keep the vials in the outer carton in order to protect from light.
Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What Depo-Medrone with Lidocaine contains
The active substances are methylprednisolone acetate and lidocaine hydrochloride monohydrate. Each millilitre of this medicine contains 40 mg of methylprednisolone acetate and 10 mg of lidocaine hydrochloride monohydrate.

The other ingredients are: sodium chloride, miripirium chloride, benzyl alcohol (E1519), macrogol, sodium hydroxide, hydrochloric acid and water for injection (see section 2 “Depo-Medrone with Lidocaine contains benzyl alcohol and sodium”).

What Depo-Medrone with Lidocaine looks like and contents of the pack
Depo-Medrone with Lidocaine is a white, sterile suspension for injection contained in a glass vial fitted with a rubber cap.

Depo-Medrone with Lidocaine is available in packs containing 1 or 10 vials, containing 2 ml of suspension.

Not all pack sizes may be marketed.

Marketing Authorisation Holder
Pfizer Healthcare Ireland
9 Riverwalk
National Digital Park
Citywest Business Campus
Dublin 24

Manufacturer
Pfizer Manufacturing Belgium NV
Rijksweg 12
Puurs, B-2870
Belgium

Company Contact address:
For further information on your medicine contact Medical Information at the following address:
Pfizer Healthcare Ireland
9 Riverwalk
National Digital Park
Citywest Business Campus
Dublin 24
Ireland
Telephone: 1800 633 363

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The following information is intended for healthcare professionals only:

PHYSICIAN LEAFLET
Depo-Medrone 40 mg/ml with Lidocaine 10 mg/ml Suspension for Injection
methylprednisolone acetate and lidocaine hydrochloride monohydrate

FOR FURTHER INFORMATION PLEASE REFER TO THE SUMMARY OF PRODUCT CHARACTERISTICS.

Posology and method of administration
Depo-Medrone with Lidocaine should not be mixed with any other preparation as flocculation of the product may occur. Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration whenever suspension and container permit.

Therapy with Depo-Medrone with Lidocaine does not obviate the need for the conventional measures usually employed. Although this method of treatment will ameliorate symptoms, it is in no sense a cure and the hormone has no effect on the cause of the inflammation.

Depo-Medrone with Lidocaine may be used by any of the following routes: intra-articular, periarticular, intrabursal, and into the tendon sheath. It **must not** be used by the intrathecal or intravenous routes.

Undesirable effects may be minimised by using the lowest effective dose for the minimum period.

Depo-Medrone with Lidocaine vials are intended for single dose use only.

Intra-articular: Rheumatoid arthritis, osteoarthritis. The dose of Depo-Medrone with Lidocaine depends on the size of the joint and the severity of the condition. Repeated injections, if needed, may be given at intervals of one to five or more weeks depending upon the degree of relief obtained from the initial injection. A suggested dosage guide is: large joint (knee, ankle, shoulder), 20 – 80 mg (0.5 – 2 ml); medium joint (elbow, wrist), 10 – 40 mg (0.25 – 1 ml); small joint (metacarpophalangeal, interphalangeal, sternoclavicular, acromioclavicular), 4 – 10 mg (0.1 – 0.25 ml).

Periarticular: Epicondylitis. Infiltrate 4 – 30 mg (0.1 – 0.75 ml) into the affected area.

Intrabursal: Subacromial bursitis, prepatellar bursitis, olecranon bursitis. For administration directly into bursae, 4 – 30 mg (0.1 – 0.75 ml). In most acute cases, repeat injections are not needed.

Into the tendon sheath: Tendinitis, tenosynovitis, epicondylitis. For administration directly into the tendon sheath, 4 – 30 mg (0.1 – 0.75 ml). In recurrent or chronic conditions, repeat injections may be necessary. In many cases, a single injection causes a marked decrease in the size of the cystic tumour and may effect a disappearance.

Intra-articular injections should be made using precise, anatomical localisation into the synovial space of the joint involved. The injection site for each joint is determined by that location where the synovial cavity is most superficial and most free of large vessels and nerves. Suitable sites for intra-articular injection are the knee, ankle, wrist, elbow, shoulder, phalangeal and hip joints. The spinal joints, unstable joints and those devoid of synovial space are not suitable. Treatment failures are most frequently the result of failure to enter the joint space, however, treatment failure may also occur despite a proper injection into the synovial space as confirmed by aspiration of fluid. Intra-articular injections should be made with care as follows: ensure correct positioning of the needle into the synovial space and aspirate a few drops of joint fluid. The aspirating syringe should then be replaced by another containing Depo-Medrone with Lidocaine. To ensure position of the needle synovial fluid should be aspirated and the injection made.

After injection, the joint is moved slightly to aid mixing of the synovial fluid and the suspension. Subsequent to therapy care should be taken for the patient not to overuse the joint in which benefit has been obtained. Negligence in this matter may permit an increase in joint deterioration that will more than offset the beneficial effects of the steroid.

Intrabursal injections should be made as follows: the area around the injection site is prepared in a sterile way and local anaesthesia is administered as necessary. A 20-24 gauge needle attached to a dry syringe is inserted into the bursa and the fluid aspirated. The needle is left in place and the aspirating syringe changed for a small syringe containing the desired dose. After injection, the needle is withdrawn and a small dressing applied.

In the treatment of tenosynovitis and tendinitis, care should be taken to inject Depo-Medrone with Lidocaine into the tendon sheath rather than into the substance of the tendon. Due to the absence of a true tendon sheath, the Achilles tendon should not be injected with Depo-Medrone with Lidocaine.

The usual sterile precautions should be observed with each injection.

<u>Paediatric population</u>
Dosage should be reduced for infants and children, but should be governed more by the severity of the condition and response of the patient, than by age or size.

<u>Elderly</u>

When used according to instructions, there is no information to suggest that a change in dosage is warranted in the elderly. Treatment of elderly patients, however, particularly if long term, should be planned bearing in mind the more serious consequences of the common side-effects of corticosteroids in old age and close clinical supervision is required.

Incompatibilities
In the absence of compatibility studies, this medicinal product must not be mixed with other medicinal products.

Special precautions for storage
Do not store above 25°C.
Do not freeze.
Keep the vials in the outer carton in order to protect from light.

Special precautions for disposal and other handling
Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

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