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 to the yellow card scheme at: www.mhra.gov.uk/yellowcard
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 OUT OF THE SIGHT AND REACH OF CHILDREN.
Do not store above 25°C. Protect from freezing.
For single dose use only. Your doctor or pharmacist will discard the remaining contents after use.
Do not take this medicine after the expiry date shown on the canister after EXP. The expiry date refers to the last day of that month.
Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

5. Further information

What Depo-Medrone with Lidocaine contains
Each 1 ml contains 40mg of methylprednisolone acetate and 10mg lidocaine hydrochloride as the active ingredient.
It also contains macrogol, sodium chloride, myristyl-gamma-picolinium chloride, benzyl alcohol and sterile water for injection. It may contain sodium chloride and/or hydrochloric acid for pH adjustment.

What Depo-Medrone with Lidocaine looks like
Depo-Medrone with Lidocaine is a white, sterile aqueous suspension for injection contained in a glass vial fitted with a rubber cap and metal seal.
Depo-Medrone with Lidocaine is available in pack containing 1 vial, each containing 1 ml of suspension.

Manufacturer
This product is manufactured by Pfizer Manufacturing Belgium NV, Rijswijk 12, 2870 Puurs, Belgium.

Product Licence holder
Procured from within the EU and repackaged by the Product Licence holder: S&M Medical Ltd, Chemilines House, Alperton Lane, Wembley, HA1 2DX.

What in this leaflet

1. What Depo-Medrone with Lidocaine is and what it is used for
2. What you need to know before you use Depo-Medrone with Lidocaine
3. How to use Depo-Medrone with Lidocaine
4. Possible side effects
5. How to store Depo-Medrone with Lidocaine
6. Contents of the pack and other information

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

Depo-Medrone with Lidocaine contains methylprednisolone acetate and lidocaine hydrochloride.
Methylprednisolone belongs to a group of medicines called corticosteroids or steroids. Corticosteroids are produced naturally in your body and are important for many body functions. 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.
- Epidydilitis, tendinitis and tenosynovitis: Tennis elbow (lateral epicondylitis), inflammation in a tendon (tendinitis), 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 your 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, or any other type of reaction after taking having given Depo-Medrone with Lidocaine, or any other medicine containing a corticosteroid or local anaesthetic or any of the other ingredients of 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 have serious symptoms caused by an infection.
- If you have recently had, or are about to have any vaccination.
- If you have any furthe
### 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.

You should show your steroid card to anyone who gives you treatment, whether as a doctor or nurse while you are taking this medicine, and for 3 months after your last injection. If you are advised to hospitalise for any reason always take 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

You 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.

### 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 Lidoocaine (steroids) should not be stopped abruptly. If you stop taking any of the following conditions seek IMMEDIATE medical attention.

You should not decide whether you should continue taking your medicine:

- Allergic reactions, such as skin rash, swelling of the face or tongue and difficulty breathing.
- Serious infection:
  - In the elderly, raised pressure within the skull (increased intracranial pressure), which may cause sight disturbance.
  - In the children, an inflammation (iritis) of the cornea, the thin tissue that lines the inner wall of the abdomen and covers most of the abdominal organs. Symptoms are, the stomach (aching pain), the liver hard, or tender, the pain may be worse when the stomach is touched or when you move.
- Optic neuritis (inflammation of the optic nerve (indicated by failing eyesight). If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

### Possible side effects

- Allergic reactions, such as skin rash, swelling of the face or tongue and difficulty breathing.
- Serious infection:
  - In the elderly, raised pressure within the skull (increased intracranial pressure), which may cause sight disturbance.
  - In the children, an inflammation (iritis) of the cornea, the thin tissue that lines the inner wall of the abdomen and covers most of the abdominal organs. Symptoms are, the stomach (aching pain), the liver hard, or tender, the pain may be worse when the stomach is touched or when you move.
- Optic neuritis (inflammation of the optic nerve (indicated by failing eyesight). If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

### Possible side effects

- Allergic reactions, such as skin rash, swelling of the face or tongue and difficulty breathing.
- Serious infection:
  - In the elderly, raised pressure within the skull (increased intracranial pressure), which may cause sight disturbance.
  - In the children, an inflammation (iritis) of the cornea, the thin tissue that lines the inner wall of the abdomen and covers most of the abdominal organs. Symptoms are, the stomach (aching pain), the liver hard, or tender, the pain may be worse when the stomach is touched or when you move.
- Optic neuritis (inflammation of the optic nerve (indicated by failing eyesight). If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.
Lidocaine: Hepatic impairment

For repeat administration, the half-life of lidocaine has approximately 3-fold higher in patients with liver impairment. Pharmacokinetic data of lidocaine after intra-articular, intra-bursal and intra-articular administrations for local are not available in hepatic impairment.

Pharmacodynamics

Moderate to mild renal failure (CrCl 30-60 mL/min) does not affect lidocaine pharmacokinetics; however, it may increase the accumulation of glycinexylidide following intravenous administration. However, lidocaine clearance decreases about half and its half-life may be prolonged in patients with liver and renal failure. The pharmacokinetics of lidocaine and its main metabolite of monomethylglycine xylidine is not significantly altered in hepatoinsufficiency (patients with cirrhosis). Pharmacokinetic data of lidocaine after intra-articular, intra-bursal and intra-articular administrations for local are not available in renal impairment.

Toxicity

No dosing adjustments are necessary in renal failure.

Methylprednisolone acetate is a synthetic glucocorticoid with the actions and properties typical of members of this pharmacologic class. Methylprednisolone acetate is a close metabolite of the synthetic corticosteroids with their lower binding affinity to the corticosteroid binding globulin (CBG). Methylprednisolone acetate has a marked difference in binding affinity to CBG compared to its synthetic corticosteroid counterparts and has a lower affinity to the corticosteroid binding protein. This property means for methylprednisolone acetate, its apparent volume of distribution is higher than those of its counterparts which means the methylprednisolone acetate will remain in the tissue for a longer period of time. Furthermore, the glucocorticoid receptors and receptors for intermediates (such as the heat shock protein) are greater in the cell nucleus of the organ cells when treated with glucocorticoids. This property means the glucocorticoid receptors and receptors for intermediates will remain in the cell nucleus for a longer period of time.

Methylprednisolone acetate has a half-life of 10 hours and may accumulate in patients with compromised liver or renal function. It is not dialyzable.

Methylprednisolone acetate is a synthetic glucocorticoid with the actions and properties typical of members of this pharmacologic class. The clearance of methylprednisolone acetate is 20 to 24 hours following i.m. administration. The clearance is equal to 0.5 to 0.7 mL/min/kg body weight (see section 4.1). Methylprednisolone acetate is about 87.5% bound to erythrocytes. For the calculation of the clearance of methylprednisolone acetate (see section 4.2).

Special Populations

No pharmacokinetic studies have been performed for methylprednisolone acetate in special populations.

Special Population

No pharmacokinetic studies have been performed for methylprednisolone acetate in special populations.
Patients repeatedly taking doses in the evening.

Since mineralocorticoid secretion can be impaired, salt and/or a mineralocorticoid should be administered concurrently.

A steroid "withdrawal syndrome," seemingly unrelated to adrenal insufficiency and sometimes considered diagnostic of glucocorticoid excess, has been seen in patients treated with high doses of glucocorticoids. This syndrome includes symptoms such as: anorexia, nausea, vomiting, anorexia nervosa, muscle pain, hypokalemia, weight loss, and/oxygen. These effects are thought to be due to the loss of mineralocorticoid concentration rather than to low cortisol levels.

Because glucocorticoids can produce or aggravate Cushings syndrome, glucocorticoids should be used with caution in patients with pre-existing Cushing's disease.

There is an enhanced effect of corticosteroids on patients with hyperlipidemia.

Metabolism and Nutrition

Corticosteroids, including methyldexamethasone, can increase blood glucose levels, especially in diabetic patients. Methylprednisolone may cause an increase in blood glucose levels that may require dose adjustment.

Aspirin and nonsteroidal antiinflammatory agents should be used cautiously in conjunction with corticosteroids.

Hypertension may occur in patients taking corticosteroids, especially if depressed mood or suicidal ideation is suspected.

Patients should be made aware that propranolol and other beta blockers may affect blood pressure and heart rate.

Corticosteroids should be used with caution in patients with mild hypertension, diabetes mellitus, or hyperlipidemia.

Corticosteroids should be used with caution in patients with diabetes mellitus, including diabetic retinopathy.

Corticosteroids should be used with caution in patients who are known to have a history of peptic ulcer.

Doses of corticosteroids may need to be increased in patients with Cushing's disease.

Corticosteroids should be used with caution in patients with diabetes mellitus.

Doses of corticosteroids may need to be increased in patients with diabetes mellitus.

The use of local anesthetics such as lidocaine during labour and delivery may be associated with adverse effects on mother and fetus.

Cardiac Effects

Advantages of glucocorticoids on the cardiovascular system, such as a reduction in blood pressure and improved myocardial oxygen supply, may be beneficial in patients with chronic conditions. These effects are also associated with a reduced incidence of cardiovascular disease.

Corticosteroids can cause reduced insulin sensitivity and glucose intolerance, which may be associated with increased blood glucose levels.

Cardiac effects are commonly seen in patients with glucocorticoid treatment and may include tachycardia, palpitations, and arrhythmias.

Corticosteroids should be used with caution in patients with pre-existing cardiac disease.

Doses of corticosteroids may need to be increased in patients with pre-existing cardiac disease.

Ectopic Uterine Fibroids

Corticosteroids are not indicated for the treatment of patients with ectopic uterine fibroids.

Corticosteroids should be used with caution in patients with uterine fibroids.

The use of local anesthesia such as lidocaine during labour and delivery may be associated with adverse effects on mother and fetus.

Cardiovascular System

Corticosteroids should be used with caution in patients with cardiovascular disease.

The use of local anesthetics such as lidocaine during labour and delivery may be associated with adverse effects on mother and fetus.

Cardiac effects are commonly seen in patients with glucocorticoid treatment and may include tachycardia, palpitations, and arrhythmias.

Corticosteroids can cause reduced insulin sensitivity and glucose intolerance, which may be associated with increased blood glucose levels.

Cardiac effects are commonly seen in patients with glucocorticoid treatment and may include tachycardia, palpitations, and arrhythmias.

Corticosteroids should be used with caution in patients with pre-existing cardiac disease.

Doses of corticosteroids may need to be increased in patients with glaucoma.

The use of local anesthesia such as lidocaine during laser surgery or injection may be associated with adverse effects on mother and fetus.

Corticosteroids should be used with caution in patients with pre-existing cardiac disease.

Doses of corticosteroids may need to be increased in patients with glaucoma.

The use of local anesthesia such as lidocaine during laser surgery or injection may be associated with adverse effects on mother and fetus.

Corticosteroids should be used with caution in patients with pre-existing cardiac disease.

Doses of corticosteroids may need to be increased in patients with glaucoma.

The use of local anesthesia such as lidocaine during laser surgery or injection may be associated with adverse effects on mother and fetus.

Corticosteroids should be used with caution in patients with pre-existing cardiac disease.

Doses of corticosteroids may need to be increased in patients with glaucoma.

The use of local anesthesia such as lidocaine during laser surgery or injection may be associated with adverse effects on mother and fetus.

Corticosteroids should be used with caution in patients with pre-existing cardiac disease.

Doses of corticosteroids may need to be increased in patients with glaucoma.

The use of local anesthesia such as lidocaine during laser surgery or injection may be associated with adverse effects on mother and fetus.

Corticosteroids should be used with caution in patients with pre-existing cardiac disease.

Doses of corticosteroids may need to be increased in patients with glaucoma.

The use of local anesthesia such as lidocaine during laser surgery or injection may be associated with adverse effects on mother and fetus.

Corticosteroids should be used with caution in patients with pre-existing cardiac disease.

Doses of corticosteroids may need to be increased in patients with glaucoma.

The use of local anesthesia such as lidocaine during laser surgery or injection may be associated with adverse effects on mother and fetus.

Corticosteroids should be used with caution in patients with pre-existing cardiac disease.

Doses of corticosteroids may need to be increased in patients with glaucoma.

The use of local anesthesia such as lidocaine during laser surgery or injection may be associated with adverse effects on mother and fetus.

Corticosteroids should be used with caution in patients with pre-existing cardiac disease.

Doses of corticosteroids may need to be increased in patients with glaucoma.

The use of local anesthesia such as lidocaine during laser surgery or injection may be associated with adverse effects on mother and fetus.

Corticosteroids should be used with caution in patients with pre-existing cardiac disease.

Doses of corticosteroids may need to be increased in patients with glaucoma.

The use of local anesthesia such as lidocaine during laser surgery or injection may be associated with adverse effects on mother and fetus.

Corticosteroids should be used with caution in patients with pre-existing cardiac disease.

Doses of corticosteroids may need to be increased in patients with glaucoma.

The use of local anesthesia such as lidocaine during laser surgery or injection may be associated with adverse effects on mother and fetus.

Corticosteroids should be used with caution in patients with pre-existing cardiac disease.

Doses of corticosteroids may need to be increased in patients with glaucoma.

The use of local anesthesia such as lidocaine during laser surgery or injection may be associated with adverse effects on mother and fetus.

Corticosteroids should be used with caution in patients with pre-existing cardiac disease.

Doses of corticosteroids may need to be increased in patients with glaucoma.

The use of local anesthesia such as lidocaine during laser surgery or injection may be associated with adverse effects on mother and fetus.

Corticosteroids should be used with caution in patients with pre-existing cardiac disease.

Doses of corticosteroids may need to be increased in patients with glaucoma.

The use of local anesthesia such as lidocaine during laser surgery or injection may be associated with adverse effects on mother and fetus.

Corticosteroids should be used with caution in patients with pre-existing cardiac disease.

Doses of corticosteroids may need to be increased in patients with glaucoma.

The use of local anesthesia such as lidocaine during laser surgery or injection may be associated with adverse effects on mother and fetus.

Corticosteroids should be used with caution in patients with pre-existing cardiac disease.

Doses of corticosteroids may need to be increased in patients with glaucoma.

The use of local anesthesia such as lidocaine during laser surgery or injection may be associated with adverse effects on mother and fetus.

Corticosteroids should be used with caution in patients with pre-existing cardiac disease.

Doses of corticosteroids may need to be increased in patients with glaucoma.

The use of local anesthesia such as lidocaine during laser surgery or injection may be associated with adverse effects on mother and fetus.

Corticosteroids should be used with caution in patients with pre-existing cardiac disease.

Doses of corticosteroids may need to be increased in patients with glaucoma.

The use of local anesthesia such as lidocaine during laser surgery or injection may be associated with adverse effects on mother and fetus.

Corticosteroids should be used with caution in patients with pre-existing cardiac disease.

Doses of corticosteroids may need to be increased in patients with glaucoma.

The use of local anesthesia such as lidocaine during laser surgery or injection may be associated with adverse effects on mother and fetus.

Corticosteroids should be used with caution in patients with pre-existing cardiac disease.

Doses of corticosteroids may need to be increased in patients with glaucoma.

The use of local anesthesia such as lidocaine during laser surgery or injection may be associated with adverse effects on mother and fetus.

Corticosteroids should be used with caution in patients with pre-existing cardiac disease.

Doses of corticosteroids may need to be increased in patients with glaucoma.

The use of local anesthesia such as lidocaine during laser surgery or injection may be associated with adverse effects on mother and fetus.

Corticosteroids should be used with caution in patients with pre-existing cardiac disease.

Doses of corticosteroids may need to be increased in patients with glaucoma.

The use of local anesthesia such as lidocaine during laser surgery or injection may be associated with adverse effects on mother and fetus.

Corticosteroids should be used with caution in patients with pre-existing cardiac disease.

Doses of corticosteroids may need to be increased in patients with glaucoma.

The use of local anesthesia such as lidocaine during laser surgery or injection may be associated with adverse effects on mother and fetus.

Corticosteroids should be used with caution in patients with pre-existing cardiac disease.

Doses of corticosteroids may need to be increased in patients with glaucoma.

The use of local anesthesia such as lidocaine during laser surgery or injection may be associated with adverse effects on mother and fetus.

Corticosteroids should be used with caution in patients with pre-existing cardiac disease.

Doses of corticosteroids may need to be increased in patients with glaucoma.

The use of local anesthesia such as lidocaine during laser surgery or injection may be associated with adverse effects on mother and fetus.

Corticosteroids should be used with caution in patients with pre-existing cardiac disease.

Doses of corticosteroids may need to be increased in patients with glaucoma.

The use of local anesthesia such as lidocaine during laser surgery or injection may be associated with adverse effects on mother and fetus.

Corticosteroids should be used with caution in patients with pre-existing cardiac disease.

Doses of corticosteroids may need to be increased in patients with glaucoma.

The use of local anesthesia such as lidocaine during laser surgery or injection may be associated with adverse effects on mother and fetus.

Corticosteroids should be used with caution in patients with pre-existing cardiac disease.

Doses of corticosteroids may need to be increased in patients with glaucoma.

The use of local anesthesia such as lidocaine during laser surgery or injection may be associated with adverse effects on mother and fetus.

Corticosteroids should be used with caution in patients with pre-existing cardiac disease.

Doses of corticosteroids may need to be increased in patients with glaucoma.

The use of local anesthesia such as lidocaine during laser surgery or injection may be associated with adverse effects on mother and fetus.

Corticosteroids should be used with caution in patients with pre-existing cardiac disease.

Doses of corticosteroids may need to be increased in patients with glaucoma.

The use of local anesthesia such as lidocaine during laser surgery or injection may be associated with adverse effects on mother and fetus.