Package leaflet: Information for the patient

Depo-Medrone® 40 mg/ml Injection
(methylprednisolone acetate)
Suspension for Injection

Read all of this leaflet carefully before you start taking this medicine because it contains important information 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 possible side effects not listed in this leaflet. See section 4.
- The name of this medicine is Depo-Medrone 40 mg/ml Injection but will be referred to as Depo-Medrone throughout the remainder of this leaflet.

What is in this leaflet

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

1. WHAT DEPO-MEDRONE IS AND WHAT IT IS USED FOR

Depo-Medrone contains methylprednisolone acetate.

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.

Boosting your body with extra corticosteroid such as Depo-Medrone can help when injected into the body by a doctor or nurse, such as in or near a joint, to treat local symptoms caused by inflammatory or rheumatic conditions such as:
- **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.
- **Plantar fasciitis:** inflammation of the tissues of the sole of the foot.
- **Skin problems:** such as alopecia areata (patchy baldness), keloids (scar tissue), lichen planus or simplex (small, purplish raised patches of skin or spots), discoid lupus (round-shaped patches, often on the face) or granuloma annulare (circular warty growths).
- **Epicondylitis (tennis elbow) and tenosynovitis:** for these conditions this medicine will be injected into the tendon sheath.

Alternatively this medicine may be injected into a muscle to help treat more general (systemic) problems affecting the whole body (e.g. symptoms caused by a hypersensitivity to a medicine), or allergic, inflammatory or rheumatic problems affecting the:
- **brain** e.g. meningitis caused by tuberculosis
- **bowel** and **gut** e.g. Crohn's disease (inflammation of the gut) or ulcerative colitis (inflammation of the lower bowel)
- **joints** e.g. rheumatoid arthritis
- **lungs** e.g. asthma, tuberculosis or inflammation caused by breathing in (aspirating) vomit or stomach contents
- **skin** e.g. Stevens-Johnson syndrome (an autoimmune disorder in which an immune system causes the skin to blister and peel) or systemic lupus erythematosus (lupus).

Your doctor may use this medicine to treat conditions other than those listed above. Ask your doctor if you are unsure why you have been given this medicine.

2. WHAT YOU NEED TO KNOW BEFORE YOU ARE GIVEN DEPO-MEDRONE

Do not use Depo-Medrone if:
- You think you have ever suffered an **allergic** reaction, or any other type of reaction after being given Depo-Medrone, or any other medicine containing a corticosteroid 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.
- You get a **rash**, or another symptom of an infection.
- You have recently had, or are about to have any **vaccination.**

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

Do not inject this medicine:
- into the **Achilles tendon** (which is located behind the ankle joint), or
- directly into a **vein (intravenous)**, the spinal cord (intrathecal), the outer covering of the brain (extradural), into the nostrils (intranasal) or in the eye (intraocular).

Warnings and precautions
Talk to your doctor or nurse before taking Depo-Medrone 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.
- Severe **depression** or **manic depression** (bipolar disorder). This includes having had depression before while taking steroid medicines like Depo-Medrone, or having a family history of these illnesses.
- **Cushing's disease** (condition caused by an excess of cortisol hormone in your 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.
- 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).
- **Hyperthyroidism** (an over-active thyroid gland).
- **Joint infection**.
- **Kidney** or **liver** disease.
- **Muscle problems** (pain or weakness) have happened while taking steroid medicines in the past.
- **Myasthenia gravis** (muscle disease with muscle fatigue), or if during treatment you develop muscular disorders.
- **Osteoporosis** (brittle bones).
- **Pancreatitis** (Inflammation of the pancreas which causes severe pain in the abdomen and back).
- **Peritonitis** (Inflammation of the thin lining (peritoneum) around the gut and stomach).
- **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. Signs of scleroderma renal crisis include raised blood pressure and decreased urine production.
- **Skin abscess**.
- **Stomach ulcer** or other serious stomach or intestinal problems.
- 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.**

Depo-Medrone treatment may increase your risk of infection, may mask some signs of infections, make current infections worse, or cause old, hidden infections to come back or get worse. New infections may also appear during Depo-Medrone use. Different infections may therefore occur more easily during the treatment. Please report any signs or symptoms of infection to your doctor or nurse. Your doctor will monitor you closely, for the development of infection and consider stopping treatment or reducing the dose as needed.

Contact your doctor promptly if you experience muscle weakness, muscle aches, cramps and stiffness while using methylprednisolone. These can be symptoms of a condition called Thyrotoxic Periodic Paralysis which may occur in patients with an over-active thyroid gland (hyperthyroidism) who are treated with methylprednisolone. You may need additional treatment to alleviate this condition.

Tumour lysis syndrome can occur after treatment of a fast-growing cancer, especially certain leukemias and lymphomas (cancers of the blood) or solid tumours. As the tumour cells die, they break apart and release their contents into the blood. This causes a change in certain chemicals in the blood, which may cause damage to organs, including the kidneys, heart and liver that may lead to muscle cramping, muscle weakness, confusion, irregular heartbeat, visual loss or visual disturbances, and shortness of breath. Your doctor will monitor you closely, especially if you are at high risk of developing tumour lysis syndrome.

Contact your doctor immediately, if you experience any muscle pain, muscle weakness, and /or red-brown change in the colour of your urine as this might be a sign of rhabdomyolysis which is a severe condition involving breakdown of your muscles.

You **must** tell your doctor before you take this medicine if you have any of the conditions listed above.

Other medicines and Depo-Medrone
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 or the other medicine works:
- **Acetazolamide** - used to treat glaucoma and epilepsy.
- **Aminoglutethimide** and **cyclophosphamide** - used for treating cancer.
- **Antibacterials** (such as isoniazid, erythromycin, clarithromycin and troleandomycin).
- **Oral Anticoagulants** of the vitamin K antagonists class - used to prevent blood clotting such as acenocoumarol**,** phenindione, fluindione 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).
- **Antivirals** (such as ritonavir, indinavir) and **pharmacokinetic enhancers** (such as cobicistat) used to treat HIV infections.
- **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 and acid indigestion.
- **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 heart beat.
- **Diltiazem** - used for heart problems or high blood pressure.
- **Ethinylestradiol** and **norethindrone** - oral contraceptives.
- **Ketoconazole** or **itraconazole** - used to treat fungal infections.
- **Pancuronium, vecuronium** - or other muscle relaxants called neuromuscular blocking agents which are used in some surgical procedures.
- 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. This medicine can affect the results of some tests.

Depo-Medrone 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. There is a risk associated with low birth weight of the baby; this risk can be reduced by administering a lower dose of the medicine.

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

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.

Driving and using machines
Undesirable effects, such as dizziness, vertigo, visual disturbances and fatigue are possible after treatment with corticosteroids. If you are affected do not drive or operate machinery.

Depo-Medrone contains sodium
This medicinal product contains less than 1 mmol sodium (23 mg) per vial, that is to say essentially 'sodium-free'.

3. HOW DEPO-MEDRONE IS GIVEN TO YOU

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 (such as a doctor, nurse or dentist) while you are taking this medicine, and for 3 months after your last injection.

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 joint will depend on the size of the joint. Large joints (e.g. knee, ankle and shoulder) may require 20 - 80 mg (0.5 - 2 ml), medium sized joints (e.g. elbow or wrist) 10 - 40 mg (0.25 - 1 ml) and small joints (e.g. finger or toe joints) may require a 4 - 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 - 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.

Skin conditions - the usual dose is between 20 - 60 mg (0.5 - 1.5 ml) injected into the affected part or parts of the skin.

For other more general conditions 40 - 120 mg (1 - 3 ml) of this medicine may be injected into a large muscle.

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.

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

Depo-Medrone® 40 mg/ml Injection
(methylprednisolone acetate)
Suspension for Injection

The following information is intended for healthcare professionals only:

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

Posology and method of administration
Depo-Medrone should not be mixed with any other suspending agent or solution. Parenteral drug products should be inspected visually for particulate matter and discolouration prior to administration, whenever suspension and container permit. Depo-Medrone may be used by any of the following routes: intramuscular, intra-articular, periarticular, intrabursal, intralesional and into the tendon sheath. It must not be used by the intrathecal or intravenous routes.

Undesirable effects may be minimized by using the lowest effective dose for the minimum period (see special warnings and precautions section in SPC).

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

Adults
Intramuscular - for sustained systemic effect: Allergic conditions (asthma, drug reactions). 80 - 120 mg (2 - 3 ml).

Dermatological conditions, 40 - 120 mg (1 - 3 ml).

Rheumatic disorders and collagen diseases (rheumatoid arthritis, SLE), 40 - 120 mg (1 - 3 ml) per week.

Dosage must be individualised and depends on the condition being treated and its severity.

The frequency of intramuscular injections should be determined by the duration of the clinical response.

On average the effect of a single 2 ml (80 mg) injection may be expected to last approximately two weeks.

Intra-articular: Rheumatoid arthritis, osteo-arthritis. The dose of Depo-Medrone depends upon 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).

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

Intralesional: Keloids, localized lichen planus, localized lichen simplex, granuloma annulare, alopecia areata, and discoid lupus erythematosus. For administration directly into the lesion for local effect in dermatological conditions, 20 - 60 mg (0.5 - 1.5 ml). For large lesions, the dose may be distributed by repeated local injections of 20 - 40 mg (0.5 - 1 ml). One to four injections are usually employed. Care should be taken to avoid injection of sufficient material to cause blanching, since this may be followed by a small slough.

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

Into the tendon sheath: 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.

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

Stopping/reducing the dose of your Depo-Medrone
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 for more than 3 weeks
- have been given high doses of Depo-Medrone, over 32 mg (0.8 ml) daily, even if it was only for 3 weeks or less
- 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
Mental health problems can happen while taking steroids like Depo-Medrone (see also section 4, **Possible Side Effects**).
- 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 the problems do happen they might need treatment.

Talk to a doctor if you (or someone 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.

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 (steroids) should not be stopped abruptly. If you suffer from any of the following symptoms seek IMMEDIATE medical 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 or dizziness. This type of side effect is rare, but can be serious.
- **Pancreatitis**, stomach pain spreading 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.
- **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 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.

If you experience any of the following side effects, or notice any other unusual effects not mentioned 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
not known
- High blood pressure, symptoms of which are headaches, or generally feeling unwell.
- Problems with the pumping of your heart (heart failure) symptoms of which are swollen ankles, difficulty in breathing and palpitations (awareness of heart beat) or irregular beating of the heart, irregular or very fast or slow pulse.
- Low blood pressure, symptoms may include dizziness, fainting, lightheadedness, blurred vision, a rapid or irregular heartbeat (palpitations).
- Increase of white blood cells (leukocytosis).
- Increased clotting of the blood.
- Warmth and reddening of the skin (flushing).

Body water and salts
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
not known
- Ulcers.
- Nausea (feeling sick) or vomiting (being sick).
- Thrush in the gullet (discomfort on swallowing).
- Indigestion.
- Diarrhoea.
- Bloated stomach.
- Abdominal pain.
- Persistent hiccups, especially when high doses are taken.

Ears
not known
- A feeling of dizziness or spinning (vertigo).

Eyes
not known
- Cataracts (indicated by failing eyesight).
- Glaucoma (raised pressure within the eye, causing pain in the eyes and headaches).
- Swollen optic nerve (causing a condition called papilloedema, and 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).
- Blurred or distorted vision (due to disease of the retina and choroid membrane).

General disorders
not known
- Poor wound healing.
- Irritability in children.
- Feeling tired or unwell.
- Skin reactions at the site of injection.
- Irritability in adults.

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

Hormones and metabolic system
not known
- Slowing of normal growth in infants, children and adolescents which may be permanent.
- Round or moon-shaped face (Cushingoid facies).
- 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
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
not known
- Accumulation of fat tissue on localized parts of the body.
- 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).

Muscles, bones and joints
not known
- Aching muscles, muscle tenderness or weakness, not caused by exercise (myopathy).
- Muscle weakness or pain which in some cases can be associated with abnormal breakdown of muscle tissue (rhabdomyolysis).
- Change in urine colour to red-brown (rhabdomyolysis).
- Brittle bones (bones that break easily).
- Muscle wasting.
- Broken bones or fractures.
- 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 or spasms.
- Swollen or painful joints due to infection.
- Post injection pain flare (a temporary increase in pain at the injection site).

Nerves and mood issues
not known
Steroids including methylprednisolone 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 methylprednisolone.
- Feeling depressed, including thinking about suicide.
- Feeling high (mania) or moods that go up and down.
- 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.
- Other nervous system side effects may include convulsions (seizures), amnesia (loss of memory), cognitive disorder (mental changes), dizziness and headache.

Skin
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.
- Increased hair on the body and face (hirsutism).
- Rash, itching, hives.
- Increased sweating.
- Inflammation of the fatty tissue under the skin which can make the skin feel hard and possibly develop painful red lumps or patches (panniculitis). Panniculitis may occur following dose reduction or discontinuation of methylprednisolone and has been more frequently reported in children.

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the **Google Play** or **Apple App Store**.
By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE DEPO-MEDRONE

- **Keep out of the sight and reach of children.**
- Do not store above 25°C.
- Do not freeze.
- Keep the vial in the outer carton.
- Depo-Medrone should not be mixed with any other fluid. Discard any remaining suspension after use.
- Do not use Depo-Medrone after the expiry date which is stated on the vial and the carton after "EXP". The expiry date refers to the last day of that month.
- If your medicine becomes discoloured or shows any sign of deterioration, return it to your pharmacist.
- 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.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Depo-Medrone contains
Each ml contains 40 mg methylprednisolone acetate.
The other ingredients are sodium chloride, polyethylene glycol 3350, myristyl-gamma-picolinium chloride, sodium hydroxide, hydrochloric acid and water for injections.

What Depo-Medrone looks like and contents of the pack
Depo-Medrone is a sterile, white suspension for injection contained in a glass vial fitted with a rubber cap and a metal seal.
Depo-Medrone is available in packs containing 1, 2, 3 or 10 vials, containing 1 ml of suspension.

Manufactured by
Pfizer Manufacturing Belgium NV, Rijksweg 12, 2870 Puurs-Sint-Amands, Belgium.

Procured from within the EU. Repackaged by the Product Licence Holder: MPT Pharma Ltd., Westgate Business Park, Unit 5-7 Tintagel Way, Aldridge, Walsall, WS9 8ER.

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POM

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Special precautions should be observed when administering Depo-Medrone. Intramuscular injections should be made deeply into the gluteal muscles. The usual technique of aspirating prior to injection should be employed to avoid intravascular administration. Doses recommended for intramuscular injection must not be administered superficially or subcutaneously.

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. 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. 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 a wheal at the site made with 1 percent procaine hydrochloride solution. 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 care should be taken to inject Depo-Medrone 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.

The usual sterile precautions should be observed with each injection.

Paediatric population
Dosage may 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.

Elderly patients
When used according to instructions, there is no information to suggest that a change in dosage is warranted in the elderly. However, treatment of elderly patients, 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
None stated.

Special precautions for disposal and other handling
Keep out of the sight and reach of children. Do not store above 25°C.
Do not freeze. Keep the vial in the outer carton. Depo-Medrone should not be mixed with any other fluid. Discard any remaining suspension after use.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

Leaflet dated 4th September 2026
Leaflet coded XXXXX

Package leaflet: Information for the patient

Methylprednisolone Acetate 40 mg/ml Injection

Suspension for Injection

Read all of this leaflet carefully before you start taking this medicine because it contains important information 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 possible side effects not listed in this leaflet. See section 4.
- The name of this medicine is Methylprednisolone Acetate 40 mg/ml Injection but will be referred to as Methylprednisolone Acetate throughout the remainder of this leaflet.

What is in this leaflet

1. What Methylprednisolone Acetate is and what it is used for
2. What you need to know before you are given Methylprednisolone Acetate
3. How Methylprednisolone Acetate is given to you
4. Possible side effects
5. How to store Methylprednisolone Acetate
6. Contents of the pack and other information

1. WHAT METHYLPREDNISOLONE ACETATE IS AND WHAT IT IS USED FOR

Methylprednisolone Acetate contains methylprednisolone acetate.

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.

Boosting your body with extra corticosteroid such as Methylprednisolone Acetate can help when injected into the body by a doctor or nurse, such as in or near a joint, to treat local symptoms caused by inflammatory or rheumatic conditions such as:
- **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.
- **Plantar fasciitis:** inflammation of the tissues of the sole of the foot.
- **Skin problems:** such as alopecia areata (patchy baldness), keloids (scar tissue), lichen planus or simplex (small, purplish raised patches of skin or spots), discoid lupus (round-shaped patches, often on the face) or granuloma annulare (circular warty growths).
- **Epicondylitis (tennis elbow) and tenosynovitis:** for these conditions this medicine will be injected into the tendon sheath.

Alternatively this medicine may be injected into a muscle to help treat more general (systemic) problems affecting the whole body (e.g. symptoms caused by a hypersensitivity to a medicine), or allergic, inflammatory or rheumatic problems affecting the:
- **brain** e.g. meningitis caused by tuberculosis
- **bowel** and **gut** e.g. Crohn's disease (inflammation of the gut) or ulcerative colitis (inflammation of the lower bowel)
- **joints** e.g. rheumatoid arthritis
- **lungs** e.g. asthma, tuberculosis or inflammation caused by breathing in (aspirating) vomit or stomach contents
- **skin** e.g. Stevens-Johnson syndrome (an autoimmune disorder in which an immune system causes the skin to blister and peel) or systemic lupus erythematosus (lupus).

Your doctor may use this medicine to treat conditions other than those listed above. Ask your doctor if you are unsure why you have been given this medicine.

2. WHAT YOU NEED TO KNOW BEFORE YOU ARE GIVEN METHYLPREDNISOLONE ACETATE

Do not use Methylprednisolone Acetate if:
- You think you have ever suffered an **allergic** reaction, or any other type of reaction after being given Methylprednisolone Acetate, or any other medicine containing a corticosteroid 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.
- You get a **rash**, or another symptom of an infection.
- You have recently had, or are about to have any **vaccination.**

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

Do not inject this medicine:
- into the **Achilles tendon** (which is located behind the ankle joint), or
- directly into a **vein (intravenous)**, the spinal cord (intrathecal), the outer covering of the brain (extradural), into the nostrils (intranasal) or in the eye (intraocular).

Warnings and precautions
Talk to your doctor or nurse before taking Methylprednisolone Acetate 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.
- Severe **depression** or **manic depression** (bipolar disorder). This includes having had depression before while taking steroid medicines like Methylprednisolone Acetate, or having a family history of these illnesses.
- **Cushing's disease** (condition caused by an excess of cortisol hormone in your 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.
- 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).
- **Hyperthyroidism** (an over-active thyroid gland).
- **Joint infection**.
- **Kidney** or **liver** disease.
- **Muscle problems** (pain or weakness) have happened while taking steroid medicines in the past.
- **Myasthenia gravis** (muscle disease with muscle fatigue), or if during treatment you develop muscular disorders.
- **Osteoporosis** (brittle bones).
- **Pancreatitis** (Inflammation of the pancreas which causes severe pain in the abdomen and back).
- **Peritonitis** (Inflammation of the thin lining (peritoneum) around the gut and stomach).
- **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. Signs of scleroderma renal crisis include raised blood pressure and decreased urine production.
- **Skin abscess**.
- **Stomach ulcer** or other serious stomach or intestinal problems.
- 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.**

Methylprednisolone Acetate treatment may increase your risk of infection, may mask some signs of infections, make current infections worse, or cause old, hidden infections to come back or get worse. New infections may also appear during Methylprednisolone Acetate use. Different infections may therefore occur more easily during the treatment. Please report any signs or symptoms of infection to your doctor or nurse. Your doctor will monitor you closely, for the development of infection and consider stopping treatment or reducing the dose as needed.

Contact your doctor promptly if you experience muscle weakness, muscle aches, cramps and stiffness while using methylprednisolone. These can be symptoms of a condition called Thyrotoxic Periodic Paralysis which may occur in patients with an over-active thyroid gland (hyperthyroidism) who are treated with methylprednisolone. You may need additional treatment to alleviate this condition.

Tumour lysis syndrome can occur after treatment of a fast-growing cancer, especially certain leukemias and lymphomas (cancers of the blood) or solid tumours. As the tumour cells die, they break apart and release their contents into the blood. This causes a change in certain chemicals in the blood, which may cause damage to organs, including the kidneys, heart and liver that may lead to muscle cramping, muscle weakness, confusion, irregular heartbeat, visual loss or visual disturbances, and shortness of breath. Your doctor will monitor you closely, especially if you are at high risk of developing tumour lysis syndrome.

Contact your doctor immediately, if you experience any muscle pain, muscle weakness, and /or red-brown change in the colour of your urine as this might be a sign of rhabdomyolysis which is a severe condition involving breakdown of your muscles.

You **must** tell your doctor before you take this medicine if you have any of the conditions listed above.

Other medicines and Methylprednisolone Acetate
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 Methylprednisolone Acetate or the other medicine works:
- **Acetazolamide** - used to treat glaucoma and epilepsy.
- **Aminoglutethimide** and **cyclophosphamide** - used for treating cancer.
- **Antibacterials** (such as isoniazid, erythromycin, clarithromycin and troleandomycin).
- **Oral Anticoagulants** of the vitamin K antagonists class - used to prevent blood clotting such as acenocoumarol**,** phenindione, fluindione 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).
- **Antivirals** (such as ritonavir, indinavir) and **pharmacokinetic enhancers** (such as cobicistat) used to treat HIV infections.
- **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 and acid indigestion.
- **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 heart beat.
- **Diltiazem** - used for heart problems or high blood pressure.
- **Ethinylestradiol** and **norethindrone** - oral contraceptives.
- **Ketoconazole** or **itraconazole** - used to treat fungal infections.
- **Pancuronium, vecuronium** - or other muscle relaxants called neuromuscular blocking agents which are used in some surgical procedures.
- 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 Methylprednisolone Acetate. This medicine can affect the results of some tests.

Methylprednisolone Acetate 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. There is a risk associated with low birth weight of the baby; this risk can be reduced by administering a lower dose of the medicine.

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

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.

Driving and using machines
Undesirable effects, such as dizziness, vertigo, visual disturbances and fatigue are possible after treatment with corticosteroids. If you are affected do not drive or operate machinery.

Methylprednisolone Acetate contains sodium
This medicinal product contains less than 1 mmol sodium (23 mg) per vial, that is to say essentially 'sodium-free'.

3. HOW METHYLPREDNISOLONE ACETATE IS GIVEN TO YOU

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 (such as a doctor, nurse or dentist) while you are taking this medicine, and for 3 months after your last injection.

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 joint will depend on the size of the joint. Large joints (e.g. knee, ankle and shoulder) may require 20 - 80 mg (0.5 - 2 ml), medium sized joints (e.g. elbow or wrist) 10 - 40 mg (0.25 - 1 ml) and small joints (e.g. finger or toe joints) may require a 4 - 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 - 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.

Skin conditions - the usual dose is between 20 - 60 mg (0.5 - 1.5 ml) injected into the affected part or parts of the skin.

For other more general conditions 40 - 120 mg (1 - 3 ml) of this medicine may be injected into a large muscle.

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.

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

Methylprednisolone Acetate 40 mg/ml Injection

Suspension for Injection

The following information is intended for healthcare professionals only:

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

Posology and method of administration
Methylprednisolone Acetate should not be mixed with any other suspending agent or solution. Parenteral drug products should be inspected visually for particulate matter and discolouration prior to administration, whenever suspension and container permit. Methylprednisolone Acetate may be used by any of the following routes: intramuscular, intra-articular, periarticular, intrabursal, intralesional and into the tendon sheath. It must not be used by the intrathecal or intravenous routes.

Undesirable effects may be minimized by using the lowest effective dose for the minimum period (see special warnings and precautions section in SPC).

Methylprednisolone Acetate vials are intended for single dose use only.

Adults
Intramuscular - for sustained systemic effect: Allergic conditions (asthma, drug reactions). 80 - 120 mg (2 - 3 ml).

Dermatological conditions, 40 - 120 mg (1 - 3 ml).

Rheumatic disorders and collagen diseases (rheumatoid arthritis, SLE), 40 - 120 mg (1 - 3 ml) per week.

Dosage must be individualised and depends on the condition being treated and its severity.

The frequency of intramuscular injections should be determined by the duration of the clinical response.

On average the effect of a single 2 ml (80 mg) injection may be expected to last approximately two weeks.

Intra-articular: Rheumatoid arthritis, osteo-arthritis. The dose of Methylprednisolone Acetate depends upon 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).

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

Intralesional: Keloids, localized lichen planus, localized lichen simplex, granuloma annulare, alopecia areata, and discoid lupus erythematosus. For administration directly into the lesion for local effect in dermatological conditions, 20 - 60 mg (0.5 - 1.5 ml). For large lesions, the dose may be distributed by repeated local injections of 20 - 40 mg (0.5 - 1 ml). One to four injections are usually employed. Care should be taken to avoid injection of sufficient material to cause blanching, since this may be followed by a small slough.

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

Into the tendon sheath: 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.

If you are given more Methylprednisolone Acetate than you should
If you think you have been given too many injections of this medicine please speak to your doctor immediately.

Stopping/reducing the dose of your Methylprednisolone Acetate
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 Methylprednisolone Acetate for more than 3 weeks
- have been given high doses of Methylprednisolone Acetate, over 32 mg (0.8 ml) daily, even if it was only for 3 weeks or less
- 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 Methylprednisolone Acetate
Mental health problems can happen while taking steroids like Methylprednisolone Acetate (see also section 4, **Possible Side Effects**).
- 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 the problems do happen they might need treatment.

Talk to a doctor if you (or someone 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.

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 Methylprednisolone Acetate (steroids) should not be stopped abruptly. If you suffer from any of the following symptoms seek IMMEDIATE medical 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 or dizziness. This type of side effect is rare, but can be serious.
- **Pancreatitis**, stomach pain spreading 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.
- **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 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.

If you experience any of the following side effects, or notice any other unusual effects not mentioned 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
not known
- High blood pressure, symptoms of which are headaches, or generally feeling unwell.
- Problems with the pumping of your heart (heart failure) symptoms of which are swollen ankles, difficulty in breathing and palpitations (awareness of heart beat) or irregular beating of the heart, irregular or very fast or slow pulse.
- Low blood pressure, symptoms may include dizziness, fainting, lightheadedness, blurred vision, a rapid or irregular heartbeat (palpitations).
- Increase of white blood cells (leukocytosis).
- Increased clotting of the blood.
- Warmth and reddening of the skin (flushing).

Body water and salts
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
not known
- Ulcers.
- Nausea (feeling sick) or vomiting (being sick).
- Thrush in the gullet (discomfort on swallowing).
- Indigestion.
- Diarrhoea.
- Bloated stomach.
- Abdominal pain.
- Persistent hiccups, especially when high doses are taken.

Ears
not known
- A feeling of dizziness or spinning (vertigo).

Eyes
not known
- Cataracts (indicated by failing eyesight).
- Glaucoma (raised pressure within the eye, causing pain in the eyes and headaches).
- Swollen optic nerve (causing a condition called papilloedema, and 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).
- Blurred or distorted vision (due to disease of the retina and choroid membrane).

General disorders
not known
- Poor wound healing.
- Irritability in children.
- Feeling tired or unwell.
- Skin reactions at the site of injection.
- Irritability in adults.

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

Hormones and metabolic system
not known
- Slowing of normal growth in infants, children and adolescents which may be permanent.
- Round or moon-shaped face (Cushingoid facies).
- 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
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
not known
- Accumulation of fat tissue on localized parts of the body.
- 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).

Muscles, bones and joints
not known
- Aching muscles, muscle tenderness or weakness, not caused by exercise (myopathy).
- Muscle weakness or pain which in some cases can be associated with abnormal breakdown of muscle tissue (rhabdomyolysis).
- Change in urine colour to red-brown (rhabdomyolysis).
- Brittle bones (bones that break easily).
- Muscle wasting.
- Broken bones or fractures.
- 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 or spasms.
- Swollen or painful joints due to infection.
- Post injection pain flare (a temporary increase in pain at the injection site).

Nerves and mood issues
not known
Steroids including methylprednisolone 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 methylprednisolone.
- Feeling depressed, including thinking about suicide.
- Feeling high (mania) or moods that go up and down.
- 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.
- Other nervous system side effects may include convulsions (seizures), amnesia (loss of memory), cognitive disorder (mental changes), dizziness and headache.

Skin
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.
- Increased hair on the body and face (hirsutism).
- Rash, itching, hives.
- Increased sweating.
- Inflammation of the fatty tissue under the skin which can make the skin feel hard and possibly develop painful red lumps or patches (panniculitis). Panniculitis may occur following dose reduction or discontinuation of methylprednisolone and has been more frequently reported in children.

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the **Google Play** or **Apple App Store**.
By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE METHYLPREDNISOLONE ACETATE

- **Keep out of the sight and reach of children.**
- Do not store above 25°C.
- Do not freeze.
- Keep the vial in the outer carton.
- Methylprednisolone Acetate should not be mixed with any other fluid. Discard any remaining suspension after use.
- Do not use Methylprednisolone Acetate after the expiry date which is stated on the vial and the carton after "EXP". The expiry date refers to the last day of that month.
- If your medicine becomes discoloured or shows any sign of deterioration, return it to your pharmacist.
- 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.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Methylprednisolone Acetate contains
Each ml contains 40 mg methylprednisolone acetate.
The other ingredients are sodium chloride, polyethylene glycol 3350, myristyl-gamma-picolinium chloride, sodium hydroxide, hydrochloric acid and water for injections.

What Methylprednisolone Acetate looks like and contents of the pack
Methylprednisolone Acetate is a sterile, white suspension for injection contained in a glass vial fitted with a rubber cap and a metal seal.
Methylprednisolone Acetate is available in packs containing 1, 2, 3 or 10 vials, containing 1 ml of suspension.

Manufactured by
Pfizer Manufacturing Belgium NV, Rijksweg 12, 2870 Puurs-Sint-Amands, Belgium.

Procured from within the EU. Repackaged by the Product Licence Holder: MPT Pharma Ltd., Westgate Business Park, Unit 5-7 Tintagel Way, Aldridge, Walsall, WS9 8ER.

For any information about this medicine, please contact:
MPT Pharma Ltd.
Tel: 01922 745645
Email: qa@cstpharma.co.uk

POM

PL: 33532/1447

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To request a copy of this leaflet in Braille, large print or audio please call 01922 745645 and ask for the Regulatory Department.

Special precautions should be observed when administering Methylprednisolone Acetate. Intramuscular injections should be made deeply into the gluteal muscles. The usual technique of aspirating prior to injection should be employed to avoid intravascular administration. Doses recommended for intramuscular injection must not be administered superficially or subcutaneously.

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. 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 Methylprednisolone Acetate. 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. Sub-sequent 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 a wheal at the site made with 1 percent procaine hydrochloride solution. 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 care should be taken to inject Methylprednisolone Acetate 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 Methylprednisolone Acetate.

The usual sterile precautions should be observed with each injection.

<u>Paediatric population</u>
Dosage may 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 patients</u>
When used according to instructions, there is no information to suggest that a change in dosage is warranted in the elderly. However, treatment of elderly patients, 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
None stated.

Special precautions for disposal and other handling
Keep out of the sight and reach of children. Do not store above 25°C.
Do not freeze. Keep the vial in the outer carton. Methylprednisolone Acetate should not be mixed with any other fluid. Discard any remaining suspension after use.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

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