PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

DEPO-MEDROL™ 40 mg Injection

Methylprednisolone acetate

Sugar free

Read all of this leaflet carefully before you are given or use DEPO-MEDROL

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- DEPO-MEDROL has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

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

1. What DEPO-MEDROL is and what it is used for

DEPO-MEDROL is a type of cortisone. It will be injected by a doctor to help treat symptoms caused by inflammatory conditions such as:

- *Osteoarthritis and rheumatoid arthritis:* Inflammation in joints. For these conditions this medicine will be injected directly into one or a few joint spaces
- *Bursitis:* Inflammation in the fluid containing spaces around the shoulder, knee and/or elbow joints.

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For this condition this medicine will be injected directly into one or more of these spaces

- *Epicondylitis (tennis elbow), tendinitis, ganglion and tenosynovitis*: Inflammation in a tendon (tendinitis) or a tendon's covering sheath (tenosynovitis). For these conditions this medicine will be injected into the tendon or the tendon sheath
- *Skin problems:* such as patchy baldness (alopecia areata), scar tissue (keloids), small, purplish raised patches of skin or spots (lichen planus or simplex), round-shaped patches, often on the face (discoid lupus)
- *Ulcerative colitis:* An inflammatory bowel disease that affects the colon and rectum

Alternatively, this medicine may be injected into a muscle to help treat more general problems affecting the body.

Ask your doctor or health care provider if you are unsure why you have been given this medicine.

2. What you need to know before you are given DEPO-MEDROL

DEPO-MEDROL should not be administered to you:

- if you are hypersensitive (allergic) to methylprednisolone acetate, or any of the other ingredients of DEPO-MEDROL (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 a certain type of fungal infection (systemic)
- if you have recently had, or are about to have any vaccination
- if you have suffered from tuberculosis in the past, stomach ulcer, severe mental disorder, Cushing's syndrome (high cortisol hormone levels causing effects such as round or moon-shaped face), herpes eye infection, smallpox or chickenpox

Speak to your doctor or health care provider immediately if any of the above applies to you.

DEPO-MEDROL should not be injected directly into a vein (intravenous), the spinal cord (intrathecal) or spinal column (epidural route).

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Warnings and precautions

Tell your doctor or health care provider before being given the injection:

Take special care with DEPO-MEDROL:

- if you have chickenpox, measles, shingles or herpes eye infection. If you think you have been in contact with someone with chickenpox, measles or shingles and you have not already had these illnesses, or if you are unsure if you have had them.
- if you have tuberculosis (TB) or if you have suffered tuberculosis in the past.
- if you have unusual stress
- if you have Cushing's disease (condition caused by an excess of cortisol hormone in your body)
- if you have hypothyroidism (an under-active thyroid)
- if you have sugar diabetes (or if there is a family history of diabetes)
- if you have severe depression, manic depression (bipolar disorder) or psychoses. This includes having had depression before while taking steroid medicines like DEPO-MEDROL or having a family history of these illnesses.
- if you have epilepsy, fits or seizures
- if you have myasthenia gravis (a condition causing tired and weak muscles)
- if you have glaucoma (increased pressure in the eye) or if there is a family history of glaucoma
- if you have recently suffered a heart attack
- if you have heart problems, including heart failure
- if you have thrombosis (formation of blood clots inside a blood vessel)
- if you have hypertension (high blood pressure)
- if you have peritonitis (inflammation of the thin lining (peritoneum) around the gut and stomach)
- if you have stomach ulcer or other serious stomach or intestinal problems (ulcerative colitis)
- if you have had muscle problems (pain or weakness) while taking steroid medicines in the past
- if you have 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
- if you have kidney disease

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- if you have pheochromocytoma (a tumour of your adrenal gland)
- if you have head injury or stroke
- if you have thrombophlebitis – vein problems due to thrombosis (clots in the veins) resulting in phlebitis (red, swollen and tender veins)

Your doctor may also have to monitor your treatment more closely, alter your dose or give you another medicine.

Mental problems while taking DEPO-MEDROL

Mental health problems can happen while taking steroids like DEPO-MEDROL (see section 4).

- These illnesses can be serious
- Usually they start within a few days or weeks of starting DEPO-MEDROL
- Most of these problems go away if the dose is lowered or DEPO-MEDROL is stopped. However, if the problems do happen, they might need treatment

Tell a doctor or health care provider if you 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.

Other medicines and DEPO-MEDROL

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

This includes taking medicines available without a prescription (e.g. cough and cold medicines). The use of DEPO-MEDROL with these medicines may cause undesirable interactions. Please consult your doctor or health care provider for advice.

You should tell your doctor or health care provider if you are taking any of the following medicines which can affect the way DEPO-MEDROL or the other medicine works:

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- antibiotics (such as isoniazid, erythromycin, clarithromycin and troleandomycin)
- antibiotics used to treat tuberculosis (TB) such as rifampicin
- medicines used to 'thin' the blood (anticoagulants), such as warfarin
- medicines used to treat epilepsy such as carbamazepine, phenytoin and phenobarbital
- medicines called neuromuscular blocking agents which are used in some surgical procedures such as pancuronium and vecuronium
- medicines used to help block involuntary muscle movement associated with disease called anticholinergics
- medicines used to treat myasthenia gravis (a muscle condition) called anticholinesterases (such as distigmine or neostigmine)
- medicines used to treat high blood sugar (antidiabetics)
- medicines used to stop you being sick called antiemetics (such as aprepitant and fosaprepitant)
- medicines used to treat fungal infections such as ketoconazole or itraconazole
- medicines used to treat HIV infections called HIV-protease inhibitors (such as indinavir and ritonavir)
- medicines used for treating cancer such as aminoglutethimide
- medicines used for heart problems or high blood pressure such as diltiazem
- oral contraceptives such as ethinyl estradiol and norethindrone
- medicines used to treat conditions such as severe rheumatoid arthritis, severe psoriasis or following an organ or bone marrow transplant such as ciclosporin
- medicines used following an organ transplant to prevent rejection of the organ such as tacrolimus
- medicines used to treat mild to moderate pain such as aspirin and other non-steroidal anti-inflammatory drugs (also called NSAIDs)
- medicines used to increase the excretion of urine called diuretics (sometimes called water tablets)
- medicines used to treat asthma such as xanthines or beta2 agonists

If you are taking long-term medicine(s)

If you are being treated for sugar diabetes, high blood pressure, heart failure or other causes of water retention (oedema), tell your doctor as he/she may need to adjust the dose of the medicines used to

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treat these conditions.

Before you have any operation, tell your doctor or health care provider that you are taking DEPO-MEDROL.

If you require a test to be carried out by your doctor or in hospital, it is important that you tell the doctor or health care provider that you are taking DEPO-MEDROL as this medicine can affect the results of some tests.

DEPO-MEDROL with food and drink

Do not drink grapefruit juice while receiving DEPO-MEDROL.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

Safety in pregnancy and lactation has not been proven.

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

Small amounts of corticosteroid medicines may get into your breast milk. This may suppress growth in the nursing infant.

Driving and using machines

DEPO-MEDROL may make you feel tired, dizzy or may affect your vision after treatment.

If you are affected, do not drive or operate any tools or machinery.

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It is not always possible to predict to what extent DEPO-MEDROL may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which DEPO-MEDROL affects them.

3. HOW TO RECEIVE DEPO-MEDROL

Do not share medicines prescribed for you with any other person.

While you are receiving DEPO-MEDROL, you should tell any health care provider who gives you treatment that you are taking DEPO-MEDROL.

You will not be expected to give yourself DEPO-MEDROL. It will be given to you by a person who is qualified to do so.

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 or health care provider will inject you with the lowest dose for the shortest possible time to get effective relief of your symptoms.

Adults

Your doctor or health care provider will tell you how many injections you will require for the condition you are being treated for, and when you will get them.

Elderly

Treatment will normally be the same as for younger adults.

Children

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

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If you have the impression that the effect of DEPO-MEDROL is too strong or too weak, tell your doctor or pharmacist.

If you receive more DEPO-MEDROL than you should

Since a health care provider will administer DEPO-MEDROL, he/she will control the dosage. However, in the event of an overdosage, your doctor will manage the overdosage.

If you forget to receive DEPO-MEDROL

If you miss a dose of DEPO-MEDROL, speak to your doctor or health care provider as soon as possible.

Do not receive a double dose to make up for forgotten individual dose.

Since a health care provider will administer DEPO-MEDROL, it is unlikely that the dose will be missed.

Effects when treatment with DEPO-MEDROL is stopped

Your doctor will decide when it is time to stop your treatment.

You may need to come off DEPO-MEDROL slowly to avoid withdrawal symptoms. These symptoms may include loss of appetite, nausea, vomiting, lack of energy, headache, fever, joint pain, peeling of the skin, muscle pain, weight loss, low blood pressure, depressed mood and thoughts of suicide.

If your symptoms seem to return or get worse as your dose of DEPO-MEDROL is reduced, tell your doctor or health care provider immediately.

4. Possible side effects

DEPO-MEDROL can have side effects.

Not all side effects reported for DEPO-MEDROL are included in this leaflet. Should your general health

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worsen or if you experience any untoward effects while taking DEPO-MEDROL, please consult your health care provider for advice.

In certain medical conditions, medicines like DEPO-MEDROL (steroids) should not be stopped abruptly. If you suffer from any of the following symptoms seek medical attention immediately. Your doctor will then decide whether you should continue taking DEPO-MEDROL.

Tell your doctor immediately if any of the following happens:

- Allergic reactions, such as skin rash, swelling of the face or wheezing and difficulty breathing.
- Angioedema - swelling below the skin's surface (may include welts).
- Pancreatitis - stomach pain which may spread through to your back, possibly accompanied by vomiting, shock and loss of consciousness.
- Burst or bleeding ulcers - symptoms of which are severe stomach pain which may go through to the back and could be associated with bleeding from the back passage, black or blood-stained stools and/or vomiting blood.
- Infections - DEPO-MEDROL 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. DEPO-MEDROL 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 may include the stomach (abdomen) being very painful or tender, the pain may become worse when the stomach is touched or when you move.

If you experience any of the following side effects, or notice any other unusual effects not mentioned in this leaflet, tell your doctor or health care provider as soon as possible.

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Frequent side effects

- round or moon-shaped face (Cushingoid)
- fluid retention, which causes swelling that may be widespread, or confined to a limb or part of a limb
- sodium retention, which causes thirst due to dehydration
- low levels of potassium in the blood
- DEPO-MEDROL can cause serious mental health problems
    - feeling depressed
    - feeling high (mania)
- cataracts
- high blood pressure, symptoms of which are headaches, or generally feeling unwell
- ulcers, including perforated and bleeding ulcers
- thinning of skin
- acne
- bruising
- muscle weakness
- brittle bones (bones that break easily)
- slowing of normal growth
- swelling of your extremities e.g. hands and feet
- poor wound healing

Less frequent side effects

- formation of a blood clot inside a blood vessel, obstructing the flow of blood through the circulatory system
- problems with the pumping of your heart (heart failure), symptoms of which are swollen ankles, difficulty in breathing and palpitations (awareness of heartbeat) or irregular beating of the heart, irregular or very fast or slow pulse
- low blood pressure, symptoms may include dizziness, fainting, light headedness, blurred vision, rapid or irregular heartbeat (palpitations)
- increased number of white blood cells (leucocytosis)

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- hypopituitarism – a short supply of one or more pituitary hormones. this can affect a number of things including growth (in children, poor overall growth and short height; in adults, reduced energy), blood pressure (may be lowered) and reproduction (in women, periods may stop; in men, decreased sperm production and loss of sexual function; in children, delayed puberty may occur)
- diabetes or worsening of existing diabetes
- increased appetite and weight gain
- abnormal localised or tumour-like accumulations of fat in the tissues
- increased cholesterol and fats in the blood
- alkalosis – the blood becoming too alkaline. This may cause irritability, muscle twitching and cramps, and tingling in the fingers, toes and around the lips
- lipomatosis – fatty growths
- steroid withdrawal syndrome, which may cause loss of appetite, nausea, vomiting, lack of energy, headache, fever, joint pain, peeling of the skin, muscle pain, weight loss, low blood pressure, depressed mood and thoughts of suicide
- DEPO-MEDROL can cause serious mental health problems
    - thinking about suicide
    - moods that go up and down (mood swings)
    - psychotic disorder including feeling, seeing or hearing things which are not there
    - feeling anxious, having problems sleeping
    - changes to personality and behaviour (the way you act), being confused
- other nervous system side effects may include convulsions (fits/seizures), amnesia (loss of memory), changes in the way you think, dizziness and headache
- increase in the pressure in your head (brain)
- back pain or weakness (due to epidural lipomatosis, a disorder in which an abnormal amount of fat is deposited on or outside the lining of the spine). Pins and needles and paralysis may also be experienced
- a feeling of dizziness or spinning (vertigo)
- glaucoma (raised pressure within the eye, causing pain in the eyes and headaches)
- protruding of the eyeballs (exophthalmos)

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- blurred or distorted vision (due to a disease called central serious chorioretinopathy) with detachment of the retina
- blindness
- blockage of the main artery in the lung (pulmonary embolism)
- hiccups
- feeling or being sick
- indigestion
- diarrhoea
- bloated stomach
- abdominal pain
- inflammation of the oesophagus (oesophagitis) – the tube that leads from your throat to stomach, including ulcers of the oesophagus
- gut perforation – a hole develops in the wall of the intestines
- stretch marks
- small purple/red patches/blisters 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, reddening of the skin
- increased sweating
- muscle wasting
- bone 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
- joint disease, pain or swelling
- irregular or absent period (menstruation)
- irritability
- feeling tired or unwell

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- skin reactions at the site of injection
- abscess
- infections at the site of injection
- increase in the pressure in the eye
- abnormal liver functions
- increased levels of blood fats (cholesterol)
- increased calcium in the urine, increase in the level of urea in the blood
- change normal reactions to skin tests, such as that for tuberculosis
- fractures in the spine
- tearing (rupturing) of tendons

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reactions Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8.

By reporting side effects, you can help provide more information on the safety of DEPO-MEDROL.

5. How to store DEPO-MEDROL

- Store all medicines out of reach of children.
- Store at or below 30 °C.
- Do not use this medicine after the expiry date stated on the label and carton.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What DEPO-MEDROL contains

The active substance is methylprednisolone acetate.

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Each 1 mL solution contains 40 mg methylprednisolone acetate.

The other ingredients are polyethylene glycol, sodium chloride, myristyl-gamma-picolinium chloride and water for injection.

What DEPO-MEDROL looks like and contents of the pack

DEPO-MEDROL is a milky suspension.

1 mL, 2 mL and 5 mL vials.

Holder of Certificate of Registration

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