PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

SOLU-MEDROL™ 40 mg Injection

SOLU-MEDROL™ 125 mg Injection

SOLU-MEDROL™ 500 mg Injection

SOLU-MEDROL™ 1 000 mg Injection

Methylprednisolone sodium succinate

SOLU-MEDROL 40 mg injection contains sugar

SOLU-MEDROL 125 mg, 500 mg and 1 000 mg injection are sugar free

Each 1 mL SOLU-MEDROL 40 mg injection contains 23,7 mg sucrose

Read all of this leaflet carefully before you are given SOLU-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.

What is in this leaflet

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

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

SOLU-MEDROL is used to suppress severe allergic or hypersensitivity reactions, the immune system of the body, or inflammation associated with disease conditions or disorders that do not respond to other therapy. It is used in conjunction with anti-cancer medicines and as replacement therapy in adrenal gland failure. SOLU-MEDROL may also be prescribed to treat conditions other than those listed above.

2. What you need to know before you use SOLU-MEDROL

SOLU-MEDROL should not be administered to you

- if you are hypersensitive (allergic) to methylprednisolone sodium succinate, or to any of the other ingredients of SOLU-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 a history of ulcers
- if you suffer from osteoporosis or any kind of mental illness
- if you have brain injury due to trauma

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

SOLU-MEDROL should not be injected directly into the spinal cord (intrathecal), or by the epidural route.

Warnings and precautions

Tell your doctor or health care provider before being given SOLU-MEDROL:

- if you have chickenpox, measles or shingles. 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 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 previously while using steroid medicines like SOLU-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. You

should have your eyes examined regularly.

- 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 stomach ulcer or other serious stomach or intestinal problems (ulcerative colitis)
- if you have muscle problems (pain or weakness) that have happened while using steroid medicines in the past
- if you have kidney disease
- if you have pheochromocytoma (a tumour of your adrenal gland)
- if you have head injury or stroke

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

Mental problems while using SOLU-MEDROL

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

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

Tell your 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.

Children and adolescents

- Your doctor will monitor the growth of your child while on treatment with SOLU-MEDROL.
- Tell your doctor if you notice that your child is disorientated, confused or experiencing headaches, as this may be a sign of raised pressure around the brain.

- Tell your doctor if your child complains of stomach pain, fever, nausea and vomiting, as this may indicate inflammation of the pancreas.

Other medicines and SOLU-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 SOLU-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 SOLU-MEDROL or the other medicine works:

- 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 (phenobarbitone)
- Medicines called neuromuscular blocking medicines 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 xanthenes 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 treat these conditions.

Before you have any operation, tell your doctor or health care provider that you are using SOLU-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 using SOLU-MEDROL as this medicine can affect the results of some tests.

SOLU-MEDROL with food and drink

Do not drink grapefruit juice while receiving SOLU-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 using this medicine.

Safety in pregnancy and lactation have not been established.

Cataracts and low birth weight 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 and harm your baby.

Driving and using machines

SOLU-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.

It is not always possible to predict to what extent SOLU-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 SOLU-MEDROL affects them.

SOLU-MEDROL 500 mg and 1000 mg contain benzyl alcohol

SOLU-MEDROL 500 mg and 1000 mg contain benzyl alcohol and must not be given to premature or newborn babies. It may cause toxic and allergic reactions in infants and children.

SOLU-MEDROL 40 mg contains sucrose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before using this medicine.

3. How to use SOLU-MEDROL

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

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

Your doctor will decide on whether to inject into a vein (intravenous) or into a muscle (intramuscular),

how much SOLU-MEDROL, 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.

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

If you are given more SOLU-MEDROL than you should

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

If you forget to use SOLU-MEDROL

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

If you miss a dose of SOLU-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 doses.

If you stop using SOLU-MEDROL

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

You will need to come off SOLU-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 SOLU-MEDROL is reduced, tell your doctor or health care provider immediately.

4. Possible side effects

SOLU-MEDROL can have side effects.

Not all side effects reported for SOLU-MEDROL are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using SOLU-MEDROL, please consult your health care provider for advice.

In certain medical conditions, medicines like SOLU-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 using SOLU-MEDROL.

If any of the following happens, stop SOLU-MEDROL, and tell your doctor immediately or go to the casualty department at your nearest hospital:

- **Allergic reactions**, such as skin rash, swelling of the face or wheezing and difficulty breathing. This type of side effect is rare but can be serious.
- **Angioedema** – swelling below the skin's surface (may include welts).

These are all very serious side effects. If you have them, you may have had a serious reaction to SOLU-MEDROL. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any

of the following:

- **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** - SOLU-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. SOLU-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.

These are all serious side effects. You may need urgent medical attention.

If you experience any of the following side effects, tell your doctor or health care provider as soon as possible.

Less frequent side effects:

- Formation of a blood clot inside a blood vessel, obstructing the flow of blood through the circulatory system - you may experience pain, cramping or swelling in your leg near the thigh or calf and the skin might be warm or red in that area
- 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 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) which will cause you to feel weak, tired, experience fever and pain
- Round or moon-shaped face (Cushingoid)
- 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
- 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
- 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
- Increased cholesterol and other fats in the blood, low levels of potassium 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
- Metabolic acidosis – when the body produces too much acid
- 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
- Increase in level of urea in the blood which is an indication of an imbalance in the level of nitrogen in the body due to the breakdown of protein – symptoms may include disorientation, fatigue or sluggishness, a pale skin, dry mouth, increased thirst, reduced urine output, rapid heart rate, swelling and loss of consciousness
- SOLU-MEDROL can cause serious mental health problems:
    - Feeling depressed, including thinking about suicide
    - Feeling high (mania) or moods that go up and down (mood swings)
    - Psychotic disorder including feeling, seeing or hearing things which are not there and

schizophrenia

- 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); you may experience headaches as a result
- 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)
- Cataracts - you may experience blurred, cloudy vision, difficulty with night vision, increased sensitivity to light
- Glaucoma (raised pressure within the eye, causing pain in the eyes and headaches)
- Protruding of the eyeballs (exophthalmos)
- Blurred or distorted vision (due to a disease called central serous chorioretinopathy) with detachment of the retina
- Blockage of the main artery in the lung (pulmonary embolism)
- Hiccups
- Ulcers, including perforated and bleeding ulcers
- 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
- Acne
- Thinning of skin, stretch marks
- Bruising

- Small purple/red patches/blisters on the skin
- Pale 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
- Peripheral oedema – swelling of your extremities e.g. hands and feet
- Muscle weakness
- Brittle bones (bones that break easily)
- Muscle wasting
- Bone fractures
- Breakdown of bone due to poor circulation of blood, this causes pain in the hip
- Joint pain
- Muscle pain
- Joint disease, pain or swelling
- Slowing of normal growth
- Irregular or absent period (menstruation)
- Poor wound healing
- Feeling tired or unwell
- Skin reactions at the site of injection
- Changes to test results and investigations that your doctor will perform
    - Increase in the pressure in the eye
    - Abnormal liver functions
    - Increased levels of blood fats (cholesterol)
    - Increased calcium in the urine
    - Change in normal reactions to skin tests, such as that for tuberculosis
    - Blood potassium decreased
    - Carbohydrate tolerance decreased
- Fractures in the spine.
- Tearing (rupturing) of tendons.

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

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. 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 SOLU-MEDROL.

5. How to store SOLU-MEDROL

Unreconstituted medicine:

Store at or below 25 °C.

Reconstituted solution:

SOLU-MEDROL 40 mg

Store reconstituted solution below 25 °C and use immediately or store reconstituted solution at 2 to 8°C and use within 48 hours.

SOLU-MEDROL 125 mg

Store reconstituted solution below 25 °C and use within 24 hours or store reconstituted solution at 2 to 8°C and use within 72 hours.

SOLU-MEDROL 500 mg and 1000 mg

Store reconstituted solution below 25 °C and use within 12 hours.

Store all medicines out of reach of children.

Do not use SOLU-MEDROL after the expiry date stated on the label and carton.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What SOLU-MEDROL contains

The active substance is methylprednisolone sodium succinate.

SOLU-MEDROL 40 mg: Each 1 mL (when mixed) contains methylprednisolone sodium succinate

equivalent to 40 mg methylprednisolone.

SOLU-MEDROL 125 mg: Each 2 mL (when mixed) contains methylprednisolone sodium succinate equivalent to 125 mg methylprednisolone.

SOLU-MEDROL 500 mg: Each 8 mL (when mixed) contains methylprednisolone sodium succinate equivalent to 500 mg methylprednisolone.

SOLU-MEDROL 1 000 mg: Each 16 mL (when mixed) contains methylprednisolone sodium succinate equivalent to 1 000 mg methylprednisolone.

SOLU-MEDROL 40 mg and 125 mg

The other ingredients are sucrose (40 mg only), monobasic sodium phosphate monohydrate, dibasic sodium phosphate dried and water for injection.

SOLU-MEDROL 500 mg and 1000 mg

The other ingredients are monobasic sodium phosphate monohydrate, dibasic sodium phosphate dried, 0,9 % m/v benzyl alcohol (preservative) and water for injection.

What SOLU-MEDROL looks like and contents of the pack

SOLU-MEDROL is a white to off-white freeze-dried cake or powder.

Sterile SOLU-MEDROL is available in the following strengths:

40 mg Act-O-Vial

125 mg Act-O-Vial

500 mg Vial with Bacteriostatic Water for Injection

1 000 mg Vial with Bacteriostatic Water for Injection

Holder of Certificate of Registration

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SOLU-MEDROL 125 mg: D/21.5.1/136

SOLU-MEDROL 500 mg: L/21.5.1/25

SOLU-MEDROL 1 000 mg: L/21.5.1/26

Bacteriostatic Water for Injection: H/34/60