PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

MEDROL® 4 mg tablets

MEDROL® 16 mg tablets

Methylprednisolone

Contains sugar (lactose monohydrate and sucrose)

Each MEDROL 4 mg tablet contains 80,0 mg lactose monohydrate and 1,50 mg sucrose.

Each MEDROL 16 mg tablet contains 159,0 mg lactose monohydrate and 2,80 mg sucrose.

Read all of this leaflet carefully before you start taking 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.
- 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 MEDROL is and what it is used for

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. MEDROL may also

be prescribed to treat conditions other than those listed above.

2. What you need to know before you take MEDROL

Do not take MEDROL:

- if you are hypersensitive (allergic) to methylprednisolone or any of the other ingredients of 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 brain injury due to trauma
- if you have recently had or are about to have any vaccination

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

Warnings and precautions

Take special care with 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 Kaposi's sarcoma (a type of skin cancer).
- 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 taking steroid medicines like 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 pancreatitis (inflammation of the pancreas which causes severe pain in the abdomen and back).
- 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 liver failure

- if you have muscle problems (pain or weakness) that have happened while taking steroid medicines in the past
- 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 increased blood pressure and decreased urine production.
- if you have kidney disease
- if you have pheochromocytoma (a tumour of your adrenal gland)
- if you have head injury or stroke

Tumour lysis syndrome (TLS) can occur after treatment of a fast-growing cancer, such as blood cancers or solid tumours. Symptoms of TLS include muscle cramping, muscle weakness, confusion, irregular heartbeat, visual loss or visual disturbances, and shortness of breath. Your health care provider will monitor you closely, especially if you are at high risk of developing tumour lysis syndrome.

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

Mental problems while taking MEDROL

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

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

Talk to 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.

Children and adolescents

Your doctor will monitor the growth of your child while on treatment with 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 their 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 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 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 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 xanthines or beta2 agonists

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 taking 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 MEDROL as this medicine can affect the results of some tests.

MEDROL with food and drink

Do not drink grapefruit juice while taking 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 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

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 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 MEDROL affects them.

MEDROL contains lactose and sucrose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking

this medicine.

3. How to take MEDROL

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

Always take MEDROL exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Adults

The normal daily dose is between 4 to 48 mg per day, depending on your condition and how severe it is. Your doctor will prescribe the lowest dose possible.

Your doctor may tell you to take your daily dose all in one go, split your daily dose throughout the day, or take it in the morning every other day.

Swallow the tablets **whole** with a drink of water.

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. Your doctor may also suggest alternate day dosing so that your child experiences fewer side effects.

Your doctor will tell you how long your treatment with MEDROL will last. Do not stop treatment early because you could make the illness worse.

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

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

If you take more MEDROL than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to take MEDROL

Wait and take the next dose as normal. Do not take a double dose to make up for forgotten individual doses.

If you stop taking MEDROL

Do not stop taking MEDROL abruptly. Your doctor will decide when it is time to stop your treatment.
You may need to come off 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 MEDROL is reduced tell your doctor or pharmacist immediately.

4. Possible side effects

MEDROL can have side effects.

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

If any of the following happens, stop taking 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 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** - 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. 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, or notice any other unusual effects not mentioned in this leaflet, tell your doctor or health care provider as soon as possible.

Tell your doctor if you notice any of the following:

Frequent side effects

- Round or moon-shaped face (Cushingoid)

- Sodium retention, which causes thirst due to dehydration
- Fluid retention, which causes swelling that may be widespread, or confined to a limb or part of a limb
- Diabetes or worsening of existing diabetes
- Muscular weakness
- Brittle bones (bones that break easily)
- Slowing of normal growth
- Poor wound healing
- Blood potassium decreased (determined by a blood test)

Less frequent side effects

- Increased number of white blood cells (leucocytosis), which will cause you to feel weak, tired, experience fever and pain
- Hypothalamic pituitary adrenal axis suppression – 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)
- Metabolic acidosis – The blood becoming too acid. It may cause rapid breathing, confusion, tiredness, headache, jaundice, and increased heart rate.
- Alkalosis – the blood becoming too alkaline. This may cause irritability, muscle twitching and cramps, and tingling in the fingers, toes and around the lips
- Alkalosis hypokalaemic – when the concentration of potassium in the blood is low
- Abnormal localised or tumour-like accumulations of fat in the tissues
- Increased appetite and weight gain
- 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
- Feeling anxious, irritated or having problems sleeping
- Changes to personality and behaviour (the way you act), being confused

- Increase in the pressure in your head (brain); you may experience headache 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
- Other nervous system side effects may include convulsions (fits/seizures), amnesia (loss of memory), changes in the way you think, dizziness and headache
- 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
- A feeling of dizziness or spinning (vertigo)
- 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
- High blood pressure, symptoms of which are headaches, or generally feeling unwell
- 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
- Low blood pressure, symptoms may include dizziness, fainting, light headedness, blurred vision, rapid or irregular heartbeat (palpitations)
- Hiccups
- Blockage of the main artery in the lung (pulmonary embolism); you may experience shortness of breath, chest pain and cough
- Ulcers, including perforated and bleeding ulcers
- Gut perforation – a hole develops in the wall of the intestines
- Feeling or being sick
- Inflammation of the oesophagus (oesophagitis) – the tube that leads from your throat to stomach, including ulcers of the oesophagus

- Indigestion
- Diarrhoea
- Bloated stomach
- Abdominal pain
- Thinning of skin, stretch marks
- Acne
- Increased hair on the body and face (hirsutism)
- Small purple/red patches/blisters on the skin
- Bruising
- Pale or darker patches on your skin or raised patches which are an unusual colour
- Increased sweating
- Rash, itching, hives, reddening of the skin
- Breakdown of bone due to poor circulation of blood, this causes pain in the hip
- Muscle wasting
- Bone fractures
- Joint pain
- Torn muscle tendons causing pain and/or swelling
- Muscle cramps or spasms
- Joint disease, pain or swelling
- Irregular or absent period (menstruation)
- Feeling tired or unwell
- The following will be determined through tests that your doctor will conduct:
    - Increase in the pressure in the eye
    - Abnormal liver functions
    - Increased levels of blood fats (cholesterol)
    - Carbohydrate tolerance decreased
    - 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

- Tearing (rupturing) of tendons
- Fractures in the spine

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 MEDROL.

5. How to store MEDROL

- Store all medicines out of reach of children
- Store at or below 25 °C.
- Do not use MEDROL 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 MEDROL contains

- The active substance is methylprednisolone.

Each MEDROL 4 mg tablet contains 4 mg methylprednisolone.

Each MEDROL 16 mg tablet contains 16 mg methylprednisolone.

- The other ingredients are lactose monohydrate, maize starch, sucrose and calcium stearate. Medrol 16 mg contains mineral oil (liquid paraffin) in addition.

What MEDROL looks like and contents of the pack

MEDROL 4 mg: Half oval, elliptical, white tablets, debossed with "MEDROL 4" on one side and double scored on the other.

MEDROL 16 mg: Elliptic, convex, white tablets engraved with “MEDROL 16” on one side and a cross score on the other.

MEDROL 4 mg tablets are available in aluminium/clear PVC foil blister strips of 30 or 100 tablets , and/or HDPE bottles containing 30 tablets.

MEDROL 16 mg tablets are available in HDPE 45 mL bottles containing 50 tablets.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

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