PATIENT INFORMATION LEAFLET

SU-MEDROL® (METHYLPREDNISOLONE ACETATE INJECTION 80mg BP)

Read all of this leaflet carefully before you start using this medicine. Keep this leaflet. You may need to read it again. If you have any further questions, ask your doctor or pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours. If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

IN THIS LEAFLET:
1. What SU-MEDROL is and what it is used for
2. Before you are given SU-MEDROL
3. How SU-MEDROL is given to you
4. Possible side effects
5. How to store SU-MEDROL
6. Further information

1. WHAT SU-MEDROL IS AND WHAT IT IS USED FOR

SU-MEDROL 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 SU-MEDROL 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 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, severe hay fever or rhinitis, tuberculosis or inflammation caused by breathing in (aspirating) vomit or stomach contents
- **skin** e.g. Stevens-Johnson syndrome (an ‘auto-immune disorder in which an immune system causes the skin to
blisters 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. BEFORE YOU ARE GIVEN SU-MEDROL
Do not use SU-MEDROL if:

- You think you have ever suffered an **allergic** reaction, or any other type of reaction after being given SU-MEDROL, or any other medicine containing a corticosteroid or any of the ingredients in this medicine (Section 6 of this leaflet contains a list of ingredients). 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.

**See your doctor immediately if you have any of the above.**

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).

**Take special care before taking SU-MEDROL:**
You **must** tell your doctor before you take this medicine 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.

- **Chickenpox, shingles** or a **herpes** eye infection. If you think you have been in contact with someone with chickenpox 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.
- **Diabetes** (or if there is a family history of diabetes)
- **Epilepsy**
- **Glaucoma** (increased pressure in the eye) or if there is a family history of glaucoma.
- You have recently suffered a **heart attack**.
- **Heart problems**, including heart failure or infections
- **Hypertension** (high blood pressure)
- **Hypothyroidism** (an under-active thyroid)
- **Joint infection**
- **Kidney** or **liver** disease
- **Muscle problems** (pain or weakness) have happened while taking steroid medicines in the past.
- **Myasthenia gravis** (a condition causing tired and weak muscles).
- **Osteoporosis** (brittle bones)
- **Skin abscess**
- **Stomach ulcer** or other serious stomach or intestinal problems
- **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

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

**Taking other medicines**
Always tell your doctor or pharmacist if you are taking any medicines (including any you have bought without a prescription) as taking SU-MEDROL with other medicines could be harmful.

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

- **Acetazolamide** - used to treat glaucoma and epilepsy
- **Aminogluthethimide** – used for treating cancer
- **Anticoagulants** - used to ‘thin’ the blood such as acenocoumarol, phenindione and warfarin
- **Anticholinesterases** - used to treat myasthenia gravis (a muscle condition) such as distigmine and neostigmine
- **Antibiotics** (such as erythromycin)
- **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 or mibebradil** – used for heart problems or high blood pressure
- **Diuretics** – sometimes called water tablets.
- **Ketoconazole or itraconazole** – used to treat fungal infections
- **Pancuronium** – or other medicines called neuromuscular blocking agents which are used in some surgical procedures
- **Rifampicin and rifabutin** – antibiotics used to treat tuberculosis (TB)
- **Vaccines** - tell your doctor or nurse if you have recently had, or are about to have any vaccination. You **should 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 operations** tell your doctor, dentist or anesthetist 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 SU-MEDROL. This medicine can affect the results of some tests.

**Pregnancy and breast feeding**
You **must** tell your doctor if you are pregnant, think you might be pregnant or are trying to become pregnant as this medicine could slow the baby’s growth.

Tell your doctor if you are breast feeding 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**
There are no special precautions while you are being treated with this medicine.

### 3. HOW SU-MEDROL IS GIVEN TO YOU

**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.

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 needed for bursitis and epicondylitis.

**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.

If you are given more SU-MEDROL 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 SU-MEDROL**
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 SU-MEDROL for more than 3 weeks;
- have been given high doses of SU-MEDROL, 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.

### 4. POSSIBLE SIDE-EFFECTS
Like all steroids 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 SU-MEDROL (steroids) should not be stopped
abruptly, if you suffer from any of the following symptoms seek IMMEDIATE medical attention, you 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. This type of side effect is rare, but can be serious.

- **Acute pancreatitis**, stomach pain spreading 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 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.

- **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:

**Body water and salts**

- 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**

- Nausea (feeling sick) or vomiting (being sick).

- Ulcers or thrush in the gullet (discomfort on swallowing).

- Indigestion.

- Bloated stomach

**Eyes**

- 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).

- Damage to the optic nerve or cataracts (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).
Hormones and metabolic system
- Slowing of normal growth in infants, children and adolescents which may be permanent.
- Irregular or no periods in women
- Increased hair on the body and face in women (hirsutism)
- Round or moon-shaped face (Cushingoid facies)
- Increased appetite and weight gain.
- Diabetes or worsening of existing diabetes
- 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 symptom if this happens, but it will show up if you have a blood test.

Immune system
- Increased susceptibility to infections which can hide or change normal reactions to skin tests, such as that for tuberculosis

Muscles, bones and joints
- Muscle weakness or wasting
- Brittle bones (bones that break easily).
- Broken bones or fractures
- Breakdown of bone due to poor circulation of blood, this causes pain in the hip
- Torn muscle tendons causing pain and/or swelling.
- Muscle cramps or spasms.
- Swollen or painful joints due to infection.

Nerves and mood issues
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 breathing problems, convulsions, dizziness, drowsiness, difficulty breathing, sensation of cold, heat or numbness, tinnitus or unconsciousness.

Skin
- Abscess, especially near injection sites
- Acne.
- Poor wound healing.
- Thinning of skin with stretch marks.
- Bruising.
- Small purple/red patches on the skin.
• Pale or darker patches on your skin, or raised patches which are an unusual color.

If you experience any of the side effects listed above tell your doctor straight away immediately

5. HOW TO STORE SU-MEDROL
This medicine must not be used after the expiry date ‘EXP’ shown on the container.
The doctor or pharmacist will keep the medicine in a safe place where children cannot reach or see it.
This medicine must be stored in a cool place, but must not be frozen.

6. FURTHER INFORMATION

What SU-MEDROL contains:
Each millilitre of this medicine contains 80 mg of Methylprednisolone Acetate as the active ingredient.
This medicine also contains sodium chloride, polyethylene glycol, myristyl-gamma picolinium chloride and water for injection.

What a SU-MEDROL looks like:
SU-MEDROL is a sterile suspension for injection contained in a glass vial fitted with a rubber cap and metal seal.
SU-MEDROL is available in packs containing 1 or 10 vials, containing 1 ml, 2 ml or 3ml of suspension.

Manufactured By:
TAJ PHARMACEUTICALS Ltd.
Mumbai, INDIA

Marketed By:
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