What is in this leaflet

Please read this leaflet carefully before you start treatment with SOLU-MEDROL. This leaflet answers some common questions about SOLU-MEDROL. It does not contain all the available information and it does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you being treated with SOLU-MEDROL against the benefits it is expected to have for you.

Follow the instructions given to you by your doctor and the advice contained in this leaflet.

If you have any concerns about being treated with this medicine, ask your doctor or pharmacist.

Keep this leaflet.
You may need to read it again.

What SOLU-MEDROL is used for

Your doctor has prescribed SOLU-MEDROL for the treatment of one or more of the following:
- skin diseases
- allergic reactions
- inflammation of the eyes
- respiratory diseases and certain respiratory infections
- diseases of the gut (gastrointestinal tract)
- multiple sclerosis
- rheumatic disorders
- diseases of the blood
- treatment of certain glandular conditions

Your doctor may have prescribed SOLU-MEDROL for another reason.

How your medicine works

Methylprednisolone sodium succinate, the active ingredient in SOLU-MEDROL, belongs to a group of medicines called corticosteroids. SOLU-MEDROL acts in the body by reducing inflammation (pain, swelling, redness and heat), which is one of the body's reactions to injury, and by reducing the body's reaction to infection.

Ask your doctor if you have any questions about why SOLU-MEDROL has been prescribed for you.

SOLU-MEDROL is available only with a doctor's prescription.
There is no evidence that SOLU-MEDROL is addictive.

Before you start treatment with SOLU-MEDROL

When you must not take it
- Do not take SOLU-MEDROL if you have an allergy to: SOLU-MEDROL or other medicines containing methylprednisolone
- any of the ingredients listed at the end of this leaflet.

Some symptoms of an allergic reaction (anaphylactic reactions) may include
- itching or hives on the skin
- difficulty breathing
- wheezing or coughing
- swelling of the face, lips, tongue or other parts of the body

If you are not sure if you have or have had an allergic reaction to SOLU-MEDROL, check with your doctor.

Do not take SOLU-MEDROL if you have a major infection.
Your doctor will advise whether use of SOLU-MEDROL is appropriate in those particular circumstances.

You must not take SOLU-MEDROL with certain types of vaccines. Tell your doctor if you have recently been vaccinated or immunised.
Your doctor will advise you whether use of SOLU-MEDROL is appropriate in those particular circumstances.

Do not administer SOLU-MEDROL intrathecally, epidurally or by local injection due to the risk of serious side effects. Do not administer this medicine to yourself.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.
If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure if you should start treatment with SOLU-MEDROL, talk to your doctor.
Before you start treatment with SOLU-MEDROL

Tell your doctor if you are allergic to any other medicines or any other substances such as foods, preservatives or dyes

Tell your doctor if you have or have had any of the following medical:

- disease of the heart
- condition of the adrenal glands
- stomach ulcers
- thin or weak bones, or bones that tend to break easily (osteoporosis)
- high blood pressure (hypertension)
- kidney or liver disease
- underactive thyroid gland
- mental disorder
- myasthenia gravis (ongoing chronic fatigue and muscle weakness)
- tuberculosis (TB)
- herpes simplex of the eye
- ulcerative colitis (disease of the bowel)
- recent head injuries
- suffers or have previously suffered from fits or convulsions

If you are scheduled to have any laboratory tests (e.g. blood or urine), tell your doctor that you are being treated with SOLU-MEDROL. The use of SOLU-MEDROL may disguise the signs of infections due to a decrease in the body's response to the infection. If you are in any doubt please consult your doctor.

Tell your doctor if you are pregnant or plan to become pregnant or are breast-feeding.

Your doctor can discuss with you the risks and benefits involved.

If you have not told your doctor about any of the above, tell him/her before you start taking SOLU-MEDROL.

Taking other medicines

Tell your doctor if you are taking any other medicines, including medicines that you buy without a prescription from a pharmacy, supermarket or health food shop.

- Some medicines and SOLU-MEDROL may interfere with each other. These include:
  - nonsteroidal anti-inflammatory such as salicylates or aspirin, medicines used to relieve pain, swelling and other symptoms of inflammation including arthritis.
  - cyclosporin, a drug used in kidney transplant patients
  - neuromuscular blocking drugs, e.g. pancuronium
  - some antibiotics, e.g. erythromycin
  - some anti-fungal agents, e.g. ketoconazole, amphoterin
  - medicines to treat blood pressure and angina
  - digoxin, a type of medicine to treat heart failure,
  - some diuretics, e.g. frusemide, a medicine to help kidneys get rid of salt and water by increasing the amount of urine produced
  - medicine for nausea e.g. aprepatint, fosaprepatint
  - oral contraceptives
  - medicines used for myasthenia gravis , glaucoma , Alzheimer's disease
  - medicines for psychiatric disorders medicines to treat anxiety
  - bronchodilators (a type of medicine that opens up the airways in the lungs) used to treat asthma, bronchitis, emphysema, and other lung diseases e.g. salbutamol
  - medicines to treat breast cancer in women who no longer have their periods because of age or have had their ovaries surgically removed
  - anticonvulsants, e.g. phenobarbitone, phenytoin
  - anticoagulants, e.g. heparin, warfarin
  - antidiabetic medicines, e.g. insulin, glibenclamide and metformin
  - immunosuppressants, e.g. methotrexate and cyclosporin
  - some immunisations, inoculations or vaccinations

You may need different amounts of SOLU-MEDROL or you may need to take different medicines. Your doctor or pharmacist can tell you what to do if you are taking any of these medicines. They also have a more complete list of medicines to be careful with or avoid while being treated with SOLU-MEDROL.

Ask your doctor or pharmacist if you are not sure if you are taking any of these medicines.

How to use SOLU-MEDROL

SOLU-MEDROL must be administered by injection (intravenous or intramuscular). It must not be given intrathecally, epidurally or by local injection due to the risk of serious side effects.

You must not administer this medicine to yourself.

SOLU-MEDROL powder is reconstituted with the diluent provided or Sterile Water for Injections by your doctor or pharmacist.

How much to use

The dose and frequency of SOLU-MEDROL that your doctor prescribes for you depends on your medical condition and also on your weight. Your doctor may change the dose and how many times a day you have it, as your condition changes.
**How long to use SOLU-MEDROL**

Your doctor will continue giving you SOLU-MEDROL for as long as your condition requires.

**If you are given too much (overdose)**

Your doctor will ensure that you receive the correct dose of SOLU-MEDROL.

You must not administer this medicine to yourself.

Overdose is unlikely with SOLU-MEDROL. However, repeated frequent doses over a long period of time may cause an increase in side effects.

Immediately telephone your doctor or Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency (Casualty) at your nearest hospital if you think that you or anyone else may have been given too much SOLU-MEDROL. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention. Keep the telephone numbers for these services handy. Have the SOLU-MEDROL box or this leaflet available to give details if needed.

**While being treated with SOLU-MEDROL**

**Things you must do**

Tell your doctor immediately if you notice any unusual symptoms.

If you are about to start taking any new medicines, tell your doctor or pharmacist that you are being treated with SOLU-MEDROL.

Tell all doctors, dentists and pharmacists who are treating you that you are being treated with SOLU-MEDROL.

If you have become pregnant while taking this medicine, tell your doctor immediately.

If you are about to have any blood test, tell you doctor that you are taking SOLU-MEDROL.

It may interfere with some of the results.

Keep all your doctor's appointments so that your progress can be checked.

**Things to be careful of**

Be careful when driving or operating machinery until you know how SOLU-MEDROL affects you. SOLU-MEDROL may cause dizziness, light headedness, visual disturbances, and fatigue in some patients. If you have any of these symptoms do not drive or operate machinery or do anything else that could be dangerous.

**Side Effects**

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are being treated with SOLU-MEDROL.

All medicines can have side effects and SOLU-MEDROL may have unwanted side effects in a few people. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

- After starting SOLU-MEDROL children may have a reduced rate of growth so your doctor may also monitor your child's height from time to time when on long term therapy

If you are over 65 years old, you may have an increased chance of side effects such as bone weakness possibly leading to fractures. You may also experience fluid retention which may lead to increased blood pressure.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor if you notice any of the following and they worry you:

- fluid retention (causes an increase in weight)
- muscle weakness or loss of muscle mass
- bone weakness possibly leading to fractures
- loss of ability to feel pain in the joint and instability of the joint
- pain when putting weight or pressure on a joint.
- increased sweating
- headache or dizziness
- changes in your menstrual periods
- mood changes and other mental disorders such as memory loss, reduced perception and problem solving abilities
- nausea and vomiting
- itchy skin and rash
- thin fragile skin or bruising
- acne
- facial redness or bands, stripes or lines on the skin
- excessive hairiness, particularly in women
- wounds that will not heal
- benign tumour like lumps as a result of fat deposits in the tissues
- persistent hiccups
- stomach pain or discomfort
- diarrhoea
- fatigue or generally feeling unwell
- pain, redness at the injection site

If these effects do not go away or they are worrying to you, tell your doctor.

Tell your doctor immediately or go to Casualty at your nearest hospital if you experience any of the following:
• signs of frequent infections such as fever, severe chills, sore throat or mouth ulcers
• allergic-type reactions, e.g. skin rash, itching and difficulty breathing, wheezing or coughing (anaphylactic reactions)
• swelling of hands, ankles or feet
• swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing
• inflammation of the food pipe
• poor appetite, fever, chills, nausea and a persistent stomach ache that becomes worse with movement.
• uncomfortable or severe stomach pains or belching after eating
• convulsions or fits
• blurred vision or loss of vision, pressure in the eye
• SOLU-MEDROL can also cause chemical imbalances in the blood and urine, swelling of the pancreas (pancreatitis), bleeding in the stomach, masking of infections, increased risk of infection, hormone changes, metabolic changes, changes in liver enzymes or increased blood pressure. Some of these side effects can only be found when your doctor does tests from time to time to check on your progress.

This is a complete list of all possible side effects. Some people may get other side effects while being treated with SOLU-MEDROL.

It is very important to tell your doctor if you notice any side effects during a course of treatment with SOLU-MEDROL.

From the pharmacy to your doctor, it is important to store it in a safe place away from heat (below 25°C).

Do not leave SOLU-MEDROL in a car.

If for any reason you take your SOLU-MEDROL home, always ensure that it is stored in a place where children cannot reach it.

Disposal

If your doctor stops treating you with SOLU-MEDROL, your hospital pharmacist will dispose of any unused medicine.

The expiry date is printed on the labels. SOLU-MEDROL should not be used after this date has passed.

Product Description

What SOLU-MEDROL looks like

SOLU-MEDROL powder for injection is a white, or nearly white powder in a vial.

This pack contains either:
• one vial with separate sections containing the powder and the liquid to dissolve the powder ready for injection (ACT-O-VIAL system), or
• two vials, one containing the powder and the other containing the liquid to dissolve the powder ready for injection, or
• five plain vials containing only the powder

Identification

SOLU-MEDROL can be identified by the Australian Registration Number on the carton:

AUST R 12342: 2g vial with diluent
AUST R 50691: 5 x 500mg plain vials
AUST R 50698: 5 x 1g plain vials

Ingredients

SOLU-MEDROL contains methylprednisolone sodium succinate as the active ingredient.

Each vial also contains the following inactive ingredients: sodium phosphate monobasic and sodium phosphate dibasic. In addition, the 40mg contain lactose.

The diluent provided for mixing contains Water for Injections.

Supplier

SOLU-MEDROL is supplied in Australia by:
Pfizer Australia Pty Ltd
ABN 50 008 422 348
38-42 Wharf Road
West Ryde NSW 2114
Toll free number: 1800 675 229

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After treatment with SOLU-MEDROL

Storage

Normally your doctor will get SOLU-MEDROL from the hospital pharmacy or their consulting rooms. If you do take your SOLU-MEDROL

SOLU-MEDROL® 4