

SOLU-MEDROL®

Methylprednisolone sodium succinate

Consumer Medicine Information

What is in this leaflet

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 treatment with SOLU-MEDROL

When SOLU-MEDROL must not be used

SOLU-MEDROL must not be used if you have an allergy to

- methylprednisolone sodium succinate
- any of the ingredients listed at the end of this leaflet.

The SOLU-MEDROL 40 mg product contains lactose from cow's milk.

Tell your doctor if you are allergic or suspect you are allergic to cow's

milk or to any other dairy products.

Some symptoms of an allergic reaction (anaphylactic reactions) may include

- skin rash
- 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 start treatment with SOLU-MEDROL, if you have a severe fungal infection.

Your doctor will advise whether use of SOLU-MEDROL is appropriate in those particular circumstances.

SOLU-MEDROL must not be used 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.

SOLU-MEDROL must be administered by intravenous or intramuscular injection.

Do not administer SOLU-MEDROL in the spinal cord (intrathecal or epidural) 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 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 conditions:

- disease of the heart, e.g., high blood pressure (hypertension) or congestive heart failure
- condition or tumour of the adrenal and/or pituitary glands
- stomach ulcers
- thin or weak bones, or bones that tend to break easily (osteoporosis)
- kidney or liver disease
- underactive thyroid gland
- emotional and mental disorder
- myasthenia gravis (ongoing chronic fatigue and muscle weakness)
- tuberculosis (TB)
- herpes simplex of the eye
- any pus producing infections
- disease of the bowel, e.g., ulcerative colitis or diverticulitis
- recent head injuries
- fits or convulsions
- diabetes or increased sugar in your blood
- blood clots
- systemic sclerosis

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.

Children

Long term treatment with corticosteroids can affect growth and development in children. It can also increase the risk of high pressure in the brain. Your doctor will monitor your child closely if your child needs long term treatment with SOLU-MEDROL.

Some of the SOLU-MEDROL products contain benzyl alcohol. Benzyl alcohol has been associated with a rare but serious side effect in infants. Your doctor will decide if treatment is appropriate.

Elderly

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.

If you have not told your doctor about any of the above, tell him/her before you start treatment with 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 food 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.
- neuromuscular blocking drugs, e.g., pancuronium

- some antibiotics, e.g., erythromycin
- medicines used to treat TB, e.g. isoniazid
- some anti-fungal agents, e.g., ketoconazole, amphotericin
- medicines to treat HIV, e.g., indinavir, ritonavir
- some medicines to treat blood pressure, heart conditions and stroke, e.g., digoxin and diltiazem
- 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., aprepitant, fosaprepitant
- 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 or hormone disorder
- anticonvulsants e.g., phenytoin, phenobarbitone
- anticoagulants e.g., heparin, warfarin
- antidiabetic medicines e.g., insulin, glibenclamide and metformin
- immunosuppressants e.g., methotrexate and cyclosporin (a medicine used in kidney transplant patients)
- some immunisations, inoculations or vaccinations
- grapefruit juice.

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.

Treatment with SOLU-MEDROL

This medicine will be administered under medical supervision.

SOLU-MEDROL must be administered by intravenous or intramuscular injection. It must not be given in the spinal cord (intrathecal or epidural) 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 SOLU-MEDROL you should be given

The dose and how often you are treated with SOLU-MEDROL will depend 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 you should be given SOLU-MEDROL

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

If you are given too much (overdose)

SOLU-MEDROL will be administered under medical supervision so an overdose is unlikely.

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 on 13 11 26 for advice, or go to Accident and Emergency (Casualty) at your nearest hospital if you think your doctor 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.

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 any doctor, dentist or pharmacist who treats you that you are being treated with SOLU-MEDROL.

Tell your doctor immediately if you become pregnant while taking SOLU-MEDROL.

If you are about to have any blood test, tell your 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

Avoid drinking grapefruit juice while you are being treated with SOLU-MEDROL.

Grapefruit may interact with SOLU-MEDROL and affect the way your body uses the medicine.

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.

Do not drive or operate machinery or do anything else that could be dangerous, if you have any of these symptoms.

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.

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:

- weight gain as a result of fluid retention or increased appetite
- muscle weakness or loss of muscle mass
- 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
- light headedness

- changes in your menstrual periods
- mood changes and other mental disorders such as memory loss, reduced perception and problem solving abilities
- nausea
- vomiting
- itchy or peeling skin
- loss of appetite or weight loss
- thin fragile skin or bruising
- acne
- facial redness or bands, stripes or lines on the skin
- excessive hairiness, particularly in women
- 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 if you experience any of the following:

- bone weakness possibly leading to fractures
- wounds that will not heal
- red, purple or brown patches on your skin
- loss of sensation or problems with your reflexes (slow or too fast)
- yellowing of the skin or eyes, dark urine, loss of appetite.

Tell your doctor immediately or go to Accident and Emergency (Casualty) at your nearest hospital if you experience any of the following:

- signs of increased pressure in the skull, including drowsiness, vomiting, headache, weakness, numbness and /or eye problems such as double vision

- 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. You may experience difficulty or pain when swallowing or heartburn
- 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 or loss of vision, distorted vision or a blind spot in your central vision, pressure in the eye
- pain and tenderness in the leg, pain on extending the foot, swelling of the lower leg, ankle and foot
- chest pain and breathlessness.

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, increased blood pressure or increased number of white blood cells (leucocytosis). 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 not 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.

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 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.

SOLU-MEDROL is supplied as:

- 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
- plain vials containing only the powder.

Available pack sizes:

- 40 mg ACT-O-VIAL - 5s pack
- 125 mg ACT-O-VIAL - 1s pack

- 500 mg vial with diluent - 1s pack
- 500mg plain vial - 1s and 5s pack
- 1g vial with diluent - 1s pack
- 1g plain vial - 1s and 5s pack

Identification

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

40 mg ACT-O-VIAL, AUST R 171991

125 mg ACT-O-VIAL, AUST R 171992

500 mg vial with diluent, AUST R 12344

1g vial with diluent, AUST R 12340

2g vial with diluent, AUST R 12342

500mg plain vial, AUST R 50691

1g plain vial, AUST R 50698.

Not all presentations are available.

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 vials provided for mixing contains Water for Injections with benzyl alcohol.

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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