SOLU-MEDROL®

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I given SOLU-MEDROL?

SOLU-MEDROL contains the active ingredient methylprednisolone sodium succinate. SOLU-MEDROL is used for treatment of various medical conditions including skin diseases, allergic reactions, inflammation of the eyes, respiratory diseases and certain respiratory infections, diseases of the gut, multiple sclerosis, rheumatic disorders, diseases of the blood and treatment of certain glandular conditions. For more information, see Section 1. Why am I given SOLU-MEDROL? in the full CMI.

2. What should I know before I receive SOLU-MEDROL?

Do not use if you have ever had an allergic reaction to methylprednisolone sodium succinate or any of the ingredients listed at the end of the CMI. Talk to your doctor if you have any other medical conditions, take

any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.
For more information, see Section 2. What should I know before I receive SOLU-MEDROL? in the full CMI.

3. What if I am taking other medicines?

Some medicines and food may interfere with SOLU-MEDROL and affect how it works. Tell your doctor if you are taking any other medicines including medicines used to relieve pain or swelling, some antibiotics, oral contraceptives, anticoagulants, anticonvulsants and antidiabetic medicines.
A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. How is SOLU-MEDROL given?

This medicine will be administered under medical supervision. SOLU-MEDROL must be administered by intravenous or intramuscular injection. You must not administer this medicine to yourself.
The dose, how often and how long 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.
More instructions can be found in Section 4. How is SOLU-MEDROL given? in the full CMI.

5. What should I know while on SOLU-MEDROL?

Things you should do	• Remind any doctor, dentist or pharmacist you visit that you are being treated with SOLU-MEDROL. • Tell your doctor immediately if you notice any unusual symptoms.
Things you should not do	• Avoid drinking grapefruit juice while you are being treated with SOLU-MEDROL.
Driving or using machines	• Be careful when driving or operating machinery until you know how SOLU-MEDROL affects you. • It may cause dizziness, light headedness, visual disturbances, and fatigue in some patients
Looking after your medicine	• Normally your doctor or hospital will store SOLU-MEDROL appropriately. It is important to store

	it in a safe place away from heat (below 25°C).

For more information, see Section 5. What should I know while on SOLU-MEDROL? in the full CMI.

6. Are there any side effects?

All medicines can have side effects and SOLU-MEDROL may have unwanted side effects in a few people.
Some of the common side effects are weight gain/loss, increased/decreased appetite, muscle weakness or loss of muscle mass, increased sweating, headache/ dizziness, light headedness, fatigue, nausea, vomiting, itchy/peeling/thin fragile skin, acne and stomach pain/ discomfort or diarrhoea. If you experience side effects such as bone weakness/fracture, wounds not healing or red/purple/brown patches of skin, yellowing of the skin/eyes, dark urine (wee), you should tell your doctor immediately. If you experience severe headache or stomach pain, blurred/double vision, convulsions or fits, chest pain or any allergic-type reactions such as skin rash, itching and difficulty breathing, tell your doctor immediately or go to Accident and Emergency at your nearest hospital.
For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

SOLU-MEDROL®

Active ingredient(s): *Methylprednisolone sodium succinate*

Consumer Medicine Information (CMI)

This leaflet provides important information about using SOLU-MEDROL. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using SOLU-MEDROL.**

Where to find information in this leaflet:

1. Why am I given SOLU-MEDROL?

SOLU-MEDROL contains the active ingredient methylprednisolone sodium succinate.

SOLU-MEDROL belongs to a group of medicine 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.

SOLU-MEDROL is used to treat 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.

There is no evidence that SOLU-MEDROL is addictive.

2. What should I know before I receive SOLU-MEDROL?

Warnings

Do not use SOLU-MEDROL if:

1. you are allergic to methylprednisolone sodium succinate or any of the ingredients listed at the end of this leaflet. The SOLU-MEDROL 40 mg product contains lactose from cow's milk.

2. Always check the ingredients to make sure you can use this medicine.
3. you have a severe fungal infection.

Check with your doctor if you:

- have or have had any other medical conditions, especially the following:
  - disease of the heart, e.g., high blood pressure (hypertension) or congestive heart failure
  - condition or tumour of the adrenal and/or pituitary glands including Cushing's syndrome
  - 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)
  - muscle pain, tenderness or weakness from other medicines, especially those used to treat high cholesterol or triglycerides
  - tuberculosis (TB)
  - herpes simplex of the eye
  - any pus producing infections or parasitic infections e.g., threadworm
  - 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
- a cancer of the blood because you may be at risk of a very rare, potentially life-threatening condition resulting from a sudden breakdown of tumour cells.

- take any medicines for any other condition
- have recently been vaccinated or immunised. SOLU-MEDROL must not be used with certain types of vaccines
- are allergic to any other medicines or any other substances such as foods, preservatives or dyes, especially cow's milk or any other dairy products.

If you are scheduled to have any laboratory tests, e.g., blood or urine (wee), 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.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. Are there any side effects?

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 them before you start treatment with SOLU-MEDROL.

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

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

3. What if I am taking other medicines?

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

Some medicines and food may interfere with SOLU-MEDROL and affect how it works. 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 (wee) produced
- medicine for nausea, e.g., aprepitant, fosaprepitant
- oral contraceptives
- medicines used for myasthenia gravis, glaucoma or 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 ciclosporin (a medicine used in kidney transplant patients)
- some immunisations, inoculations or vaccinations
- grapefruit juice.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect SOLU-MEDROL.

4. How is SOLU-MEDROL given?

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 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.

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

If you are given too much SOLU-MEDROL

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.

If you think that you have been given too much SOLU-MEDROL, you may need urgent medical attention.

You should immediately:

- contact your doctor, or
- phone the Poisons Information Centre (**by calling 13 11 26**), or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

Keep the telephone numbers for these services handy.

5. What should I know while on SOLU-MEDROL?

Things you should 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 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 you should not do

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.

Driving or using machines

Be careful before you drive or use any machines or tools 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.

Looking after your medicine

Normally your doctor or hospital will store SOLU-MEDROL appropriately, 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.

Getting rid of any unwanted medicine

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.

6. Are there any 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. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

Side effects

Common side effects	What to do
• 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	**Speak to your doctor if you have any of these common side effects and they worry you.**

Common side effects	What to do
• 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 • warmth and reddening of the skin (flushing) • excessive hairiness, particularly in women • benign tumour-like lumps as a result of fat deposits in the tissues	

Common side effects	What to do
• painful or tender bumps under the skin • persistent hiccups • stomach pain or discomfort • diarrhoea • fatigue or generally feeling unwell • pain, redness at the injection site	

Serious side effects

Serious side effects	What to do
Call your doctor immediately: • 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)	**Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.**

Serious side effects	What to do
• yellowing of the skin or eyes, dark urine (wee), loss of appetite **Seek Emergency medical attention:** • signs of increased pressure in the skull, including drowsiness, vomiting, headache, weakness, numbness and /or eye problems such as double vision • convulsions or fits • blurred or loss of vision, distorted vision or a blind spot in your central vision, pressure in the eye • 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	

Serious side effects	What to do
• 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 • severe muscle pain or weakness often along with passing of dark red or brown urine (wee), or only passing small amounts of wee • uncomfortable or severe stomach pains or belching after eating • pain and tenderness in the leg, pain on extending the foot, swelling of the lower leg, ankle and foot	

Serious side effects	What to do
• chest pain and breathlessness	

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

SOLU-MEDROL can also cause chemical imbalances in the blood and urine (wee), 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.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/safety/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What SOLU-MEDROL contains

Active ingredient **(main ingredient)**	**methylprednisolone sodium succinate**
Other ingredients **(inactive ingredients)**	**40 mg ACT-O-VIAL System** • monobasic sodium phosphate • dibasic sodium phosphate • lactose monohydrate • sodium hydroxide • water for injections (diluent) **125 mg ACT-O-VIAL System** • monobasic sodium phosphate • dibasic sodium phosphate • sodium hydroxide • water for injections (diluent)

Active ingredient **(main ingredient)**	**methylprednisolone sodium succinate**
	500 mg, 1 g and 2 g Vials with Diluent • monobasic sodium phosphate • dibasic sodium phosphate • sodium hydroxide • benzyl alcohol (diluent) • water for injections (diluent) **500 mg and 1 g Plain Vials** • monobasic sodium phosphate • dibasic sodium phosphate • sodium hydroxide

Do not use this medicine if you are allergic to any of these ingredients.

SOLU-MEDROL does not contain sucrose, gluten, tartrazine or any other azo dyes.

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 (AUST R 171991)

125 mg ACT-O-VIAL - 1s pack (AUST R 171992)

500 mg vial with diluent - 1s pack (AUST R 12344)

1 g vial with diluent - 1s pack (AUST R 12340)

2 g vial with diluent - 1s pack (AUST R 12342)

500 mg plain vial - 1s and 5s pack (AUST R 50691)

1 g plain vial - 1s and 5s pack (AUST R 50698)

Not all presentations are available.

Who distributes SOLU-MEDROL

Pfizer Australia Pty Ltd

Sydney NSW

Toll Free Number: 1800 675 229

www.pfizermedicalinformation.com.au

This leaflet was prepared in July 2025.