SOLU-CORTEF®

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 being treated with SOLU-CORTEF?

SOLU-CORTEF contains the active ingredient hydrocortisone sodium succinate. It belongs to a group of medicines called corticosteroids. SOLU-CORTEF is used to reduce inflammation (pain, swelling, redness and heat) in certain glandular disorders, rheumatic disorders, skin diseases, allergic conditions, inflammation of the eyes, stomach or gut disorders, respiratory diseases and blood disorders.

For more information, see Section 1. Why am I being treated with SOLU-CORTEF? in the full CMI.

2. What should I know before treatment with SOLU-CORTEF?

Do not use if you have ever had an allergic reaction to hydrocortisone sodium succinate or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have severe fungal infection, 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 treatment with SOLU-CORTEF? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with SOLU-CORTEF and affect how it works.

A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. How is SOLU-CORTEF given?

- SOLU-CORTEF is given as an injection into a muscle, or slowly into a vein by a doctor or nurse.
- Your doctor will decide the dose and frequency of SOLU-CORTEF depending on your condition.

More instructions for the preparation of solutions for the plain vial (powder only) or ACT-O-VIAL® (powder and diluent) system can be found in Section 4. How is SOLU-CORTEF given? in the full CMI.

5. What should I know during treatment with SOLU-CORTEF?

Things you should do	• If you get an infection or suspect an infection during a course of treatment, tell your doctor as soon as possible. • Tell your doctor if you plan to have surgery; you are about to be given a vaccine or start on any new medicine; you become pregnant during treatment, you are diabetic; or you have liver disease.
Driving or using machines	• Be careful before you drive or use any machines or tools until you know how SOLU-CORTEF affects you. • SOLU-CORTEF may cause dizziness, lightheadedness, visual disturbances, and fatigue in some people.
Drinking grapefruit juice	• Avoid drinking grapefruit juice while you are being

	treated with SOLU-CORTEF. • Grapefruit may interact with SOLU-CORTEF and affect the way your body uses the medicine.
Looking after your medicine	• Store below 25°C and protect from light. Keep in the original packaging until ready for use. • Store reconstituted diluted solutions at 2°C - 8°C for not more 24 hours. Any solution not used within 24 hours should be discarded.

For more information, see Section 5. What should I know during treatment with SOLU-CORTEF? in the full CMI.

6. Are there any side effects?

Side effects include nausea and vomiting, changes in appetite, weight gain caused by fluid retention, muscle weakness or tenderness, increased sweating, excessive thirst, changes in mood, changes in skin, excessive hairiness, tiredness or drowsiness. Serious side effects are rare and may include sudden signs of allergy, severe stomach pain, vomiting blood, or blood in the stools, convulsions or fits, changes in vision, eye infections, pain and tenderness of the lower leg, ankle and foot, chest pain and breathlessness. Long term treatment with

corticosteroids can affect growth and development in children.

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-CORTEF®

Active ingredient(s): *hydrocortisone sodium succinate*

Consumer Medicine Information (CMI)

This leaflet provides important information about using SOLU-CORTEF. **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-CORTEF.**

Where to find information in this leaflet:

1. Why am I being treated with SOLU-CORTEF?
2. What should I know before treatment with SOLU-CORTEF?
3. What if I am taking other medicines?
4. How is SOLU-CORTEF given?
5. What should I know during treatment with SOLU-CORTEF?
6. Are there any side effects?
7. Product details

1. Why am I being treated with SOLU-CORTEF?

SOLU-CORTEF contains the active ingredient hydrocortisone sodium succinate. It belongs to a group of medicines called corticosteroids. SOLU-

CORTEF acts by reducing inflammation (pain, swelling, redness and heat).

SOLU-CORTEF is an injection. It is used when oral treatment is not possible. Your doctor has prescribed SOLU-CORTEF for the treatment of one or more of the following:

- certain glandular disorders
- rheumatic disorders
- skin diseases
- allergic conditions
- inflammation of the eyes
- stomach or gut disorders
- respiratory diseases
- blood disorders

2. What should I know before treatment with SOLU-CORTEF?

Warnings

Do not use SOLU-CORTEF if you:

- are allergic to hydrocortisone sodium succinate, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine.
- have severe fungal infection.

Do not use this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

Check with your doctor if you:

- have or have had any other medical conditions, especially the following:
  - stomach or gut disorders e.g. stomach ulcers
  - disease of the heart e.g. high blood pressure (hypertension) or congestive heart failure
  - a problem with blood clots forming in your blood vessels such as painful inflammation of the veins (thrombophlebitis) or blockage of blood vessels in the legs (deep vein thrombosis or DVT), or lungs (pulmonary embolism)
  - tuberculosis
  - herpes simplex of the eye
  - chicken pox or measles
  - mental or mood disorders
  - thin or weak bones that tend to break easily (osteoporosis)
  - 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
  - underactive or overactive thyroid gland
  - condition or tumour of the adrenal and/or pituitary glands

- a solid cancer or 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
- kidney or liver disease
- recent head injuries
- fits or convulsions
- ulcerative colitis (disease of the bowel)
- diabetes or increased sugar in the blood

- take any medicines for any other condition
- have allergies to any other medicines, foods, preservatives or dyes

If you are not sure whether you should be given this medicine, talk to 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?

Before you are treated with SOLU-CORTEF:

Tell your doctor if you plan to have surgery.

The use of SOLU-CORTEF may disguise the signs of infections or make existing infections worse due to a decrease in the body's response to the infection. Talk to your doctor if you have any concerns.

Children

Long term treatment with corticosteroids can affect growth and development in children. Other side effects may occur when SOLU-CORTEF is given to children. Talk to your doctor if you have any concerns about SOLU-CORTEF being given to your child.

Growth in children may be affected by treatment with SOLU-CORTEF so your doctor may also monitor your child's height.

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 may interfere with SOLU-CORTEF and affect how it works. These include:

- non-steroidal anti-inflammatory medicines used to relieve pain, swelling and other symptoms of inflammation, including arthritis e.g. aspirin or salicylates
- some antibiotics e.g. erythromycin, clarithromycin, rifampicin
- medicines used to treat tuberculosis e.g. isoniazid
- antifungal agents e.g. ketoconazole, itraconazole
- medicines used to treat HIV e.g. indinavir, ritonavir
- some medicines used to treat blood pressure and stroke e.g. digoxin and diltiazem
- some diuretics (a medicine to help kidneys get rid of salt and water by increasing the amount of urine (wee) produced)
- medicines for nausea e.g. aprepitant, fosaprepitant
- oral contraceptives
- medicines used for myasthenia gravis, glaucoma
- medicines for psychiatric disorders
- 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
- anticonvulsants e.g. carbamazepine, phenytoin, phenobarbitone
- oral medicines to reduce blood clotting e.g. warfarin
- antidiabetic medicines e.g. insulin, glibenclamide and metformin
- immunosuppressants e.g. methotrexate or ciclosporin (a medicine used in kidney transplant patients)
- some immunization, inoculation or vaccinations

- medicine used to relieve stomach cramps or spasms, to prevent travel sickness and to treat Parkinson's disease (anticholinergics)
- medicines used to treat breast cancer or hormone disorder

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-CORTEF.
You may need different amounts of your medicines, or you may need to take different medicines.

4. How is SOLU-CORTEF given?

How much will be given

- Your doctor will decide the dose and frequency of SOLU-CORTEF depending on your medical condition.
- Your doctor may change the dose and how many times a day you are given SOLU-CORTEF as your condition changes.
- You may be given a single dose, or several doses 2 to 6 hours apart.

How is SOLU-CORTEF given

- You will not usually be handling this product directly. It will be given to you as an injection by an experienced health care professional.
- SOLU-CORTEF is given as an injection into a muscle, or as a slow injection into a vein over a period of

30 seconds to 10 minutes depending on the dose required.

- SOLU-CORTEF must not be injected into the spinal cord (intrathecal or epidural) or by any other unapproved route of administration.
- Instructions for the preparation of solutions for the 100 mg vial or the directions for using the ACT-O-VIAL system are included in the package insert.

How long is SOLU-CORTEF given

Your doctor will continue giving you SOLU-CORTEF for as long as your condition requires or before changing to another similar medicine that can be given less frequently or taken orally.

After long-term treatment with SOLU-CORTEF, your doctor will determine how to slowly withdraw the medicine.

SOLU-CORTEF is not addictive.

If too much SOLU-CORTEF is given

As SOLU-CORTEF is given by your doctor, it is unlikely that you will receive an overdose. Symptoms of an overdose may include the side effects listed under Section 6. Are there any side effects? If you think that you have been given too much SOLU-CORTEF, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or

- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

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

5. What should I know during treatment with SOLU-CORTEF?

Things you should do

Tell any doctor or nurse giving you this medicine:

- if you are about to be given a vaccine or start on any new medicine
- if you become pregnant during treatment with SOLU-CORTEF
- if you get an infection or suspect an infection during a course of treatment. Tell your doctor as soon as possible as SOLU-CORTEF may hide some signs of infection
- if you are diabetic. Your need for insulin or glucose lowering medicines may increase while being treated with SOLU-CORTEF
- if you have liver disease. Your doctor may need to monitor your response and/or adjust your dose

Tell your doctor promptly if you experience muscle weakness, muscle aches, cramps and stiffness while using SOLU-CORTEF.

Remind any doctor, dentist or pharmacist you visit that you are being treated with SOLU-CORTEF.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how SOLU-CORTEF affects you.

SOLU-CORTEF may cause dizziness, lightheadedness, visual disturbances, and fatigue in some people.

Grapefruit juice

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

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

How is SOLU-CORTEF stored

- SOLU-CORTEF will normally be stored in a hospital.
- Keep in the original packaging until ready for use.
- The undiluted product should be stored below 25°C and should be protected from light.
- The diluted/reconstituted solution should be used as soon as possible and only if it is clear. If storage is necessary, hold reconstituted diluted solutions at 2°C - 8°C for not more than 24 hours.

Keep it where young children cannot reach it.

When to discard SOLU-CORTEF

SOLU-CORTEF is used in one patient on one occasion only. Any solution not used within 24 hours should be discarded.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

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.

Side effects

Side effects	What to do
• weight gain as a result of fluid retention or increased appetite • muscle weakness or loss of muscle mass	**Speak to your doctor if you have any of these side effects and they worry you.**

Side effects	What to do
• increased sweating • headache, dizziness or light headedness • effects on your menstrual periods • mood changes and other mental disorders e.g. over-excitement, depression, suicidal thoughts, hallucinations, anxiety, irritability, feeling of confusion, memory loss, reduced perception and problem solving abilities, abnormal behaviour, addiction to drugs or medicines • itchy skin • acne • thin fragile skin, bruising or change in skin colour, redness of the skin, stretch marks, pale areas of the skin • excessive hairiness, particularly in women • excessive thirst, the passing of an increased	Do not be alarmed by this list of side effects. You may not experience any of them.

Side effects	What to do
amount of urine (wee), increase in appetite with a loss of weight, feeling tired, drowsy, weak, depressed, irritable, and generally unwell • loss of appetite, weight loss, nausea, vomiting, feeling of tiredness, drowsiness or lack of energy, headache, fever, joint pain, peeling skin, aching muscle, muscle tenderness or weakness not caused by exercise • small lumps under the skin as a result of fat deposits in the tissues • painful or tender bumps under the skin • inflammation of the food pipe. You may experience difficulty or pain when swallowing, or heartburn problems with your growth • persistent hiccups	

Side effects	What to do
• pain, redness at the injection site	

Serious side effects

Serious side effects	What to do
• bone fractures or muscle pain • wounds that will not heal • red, purple or brown patches on your skin • problems with your back, including pain or weakness • loss of sensation of problems with your reflexes (slow or too fast) • difficulty sleeping • bouts of anxiety and headaches, sweating, palpitations, dizziness, a feeling of weakness, nausea, vomiting, diarrhoea, dilated pupils and blurred vision, stomach pains, and raised blood	**Tell your doctor immediately if you experience any of these side effects.**

Serious side effects	What to do
pressure. These could be symptoms of the adrenal gland, which sits near the kidney.	
• allergic reactions e.g. skin rash, itching, difficulty breathing, wheezing or coughing • swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing • swelling of hands, ankles or feet • severe stomach pain, nausea and vomiting • sudden nausea, vomiting and diarrhoea • severe muscle pain or weakness often along with passing of dark red or brown urine (wee), or only passing small amounts of wee • sudden weakness, lethargy or fainting	**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.** These may be serious effects. You may need urgent medical attention. Serious side effects are rare.

Serious side effects	What to do
• vomiting blood or material that looks like coffee grounds • bleeding from your bottom, black sticky bowel motions (poo) or bloody diarrhoea • convulsions or fits • blurred or distorted vision or loss of vision, eye infections • pain and tenderness in the leg, pain on extending the foot • swelling of the lower leg, ankle and foot • chest pain and breathlessness	

SOLU-CORTEF may 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 to check on your progress.

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

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-CORTEF contains

Active ingredient **(main ingredient)**	Hydrocortisone sodium succinate
Other ingredients **(inactive ingredients)**	Monobasic sodium phosphate Dibasic sodium phosphate

ACT-O-VIAL® only

The diluent for the ACT-O-VIAL products consists of Water for Injections. It does not contain any antimicrobial preservative.

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

What SOLU-CORTEF looks like

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

Vials which have separate sections containing the powder and liquid to dissolve the powder ready for injection are also available (ACT-O-VIAL system).

SOLU-CORTEF 100 mg plain vial is supplied in packs of 5 vials.

SOLU-CORTEF ACT-O-VIALS 100 mg and 250 mg are supplied in packs of 1 vial.

Australian Registration Number

Plain vial (powder only):

100 mg: AUST R 12264

ACT-O-VIAL® (powder and diluent):

100 mg: AUST R 167893

250 mg: AUST R 167894.

Who distributes SOLU-CORTEF

Pfizer Australia Pty Ltd

Sydney NSW

Toll Free Number: 1800 675 229

www.pfizermedical.com.au

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