

SOLU-CORTEF®

Hydrocortisone sodium succinate

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about SOLU-CORTEF. It does not contain all the available information. 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 treating you with SOLU-CORTEF against the benefits they expect it will have for you.

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

Keep this leaflet even after your treatment with SOLU-CORTEF is finished.

You may need to read it again.

What SOLU-CORTEF is used for

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. Hydrocortisone sodium succinate, the active ingredient in SOLU-CORTEF, belongs to a group of medicines called corticosteroids.

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

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

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

SOLU-CORTEF is available only with a doctor's prescription.

SOLU-CORTEF is not addictive.

Before being treated with SOLU-CORTEF

When SOLU-CORTEF must not be given

SOLU-CORTEF must not be given if you:

- are allergic to SOLU-CORTEF, other medicines containing hydrocortisone sodium succinate
- any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin.

SOLU-CORTEF must not be given if you have a severe fungal infection

SOLU-CORTEF must not be injected into the spinal cord (intrathecal or epidural) or by any other unapproved route of administration.

SOLU-CORTEF must not be used 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 whether you should be given this medicine, talk to your doctor.

Before treatment with SOLU-CORTEF

Tell your doctor if you are allergic to any other medicines, foods, preservatives and dyes.

Tell your doctor if you are pregnant or intend to become pregnant.

Your doctor will discuss the risks and benefits of using SOLU-CORTEF when pregnant.

Tell your doctor if you are breastfeeding or plan to breastfeed.

Your doctor will discuss the risks and benefits of using SOLU-CORTEF when breastfeeding.

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

- 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 (TB)

- 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)
- underactive thyroid gland
- condition or tumour of the adrenal and/or pituitary glands
- kidney or liver disease
- recent head injuries
- fits or convulsions
- ulcerative colitis (disease of the bowel)
- diabetes or increased sugar in your blood
- blood clots.

Tell your doctor if you plan to have surgery.

The use of SOLU-CORTEF 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.

If you have not told your doctor about any of the above, tell them before you are treated with SOLU-CORTEF.

Children

Long term treatment with corticosteroids can affect growth and development in children. Other side-effects may occur when given to children. Your doctor will monitor your child closely if your child needs long term treatment with SOLU-CORTEF.

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.

In particular, tell your doctor if you are taking:

- 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 TB, e.g. isoniazid
- antifungal agents, e.g. ketoconazole, itraconazole
- medicines 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 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 cyclosporine (a medicine used in kidney transplant patients)
- some immunisation, 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
- grapefruit juice.

These medicines may be affected by SOLU-CORTEF or may affect how

well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor or other healthcare professional have more information on medicines to be careful with or avoid while taking this medicine.

How SOLU-CORTEF is 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 slowly into a vein over a period of 30 seconds to 10 minutes depending on the dose required.

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 much is given

You may be given a single dose or several doses 2 to 6 hours apart.

The dose and frequency of SOLU-CORTEF that your doctor prescribes for you depends on your medical condition. Your doctor may change the dose and how many times a day you have it, as your condition changes.

Tell your doctor if you have liver disease as your doctor may need to monitor your response and/or adjust your dose.

How long it is 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.

If you are given too much (overdose)

Overdose is unlikely as treatment will be given by your doctor. The possible effects of overdose are the same as those listed under Side Effects.

Immediately telephone your doctor or Poisons Information Centre (telephone 13 11 26) for advice, or go to Emergency (Casualty) at your nearest hospital if you think that you or anyone else may have been given too much SOLU-CORTEF. 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-CORTEF box or this leaflet available to give details if needed.

While being treated with SOLU-CORTEF

Things you must do

Tell any other doctors, dentists and pharmacists who are treating you that you are being treated with SOLU-CORTEF.

If you are about to be given a vaccine or started on any new medicine, tell your doctor, dentist or pharmacist that you are being treated with SOLU-CORTEF.

If you become pregnant while having treatment with SOLU-CORTEF tell your doctor.

SOLU-CORTEF may hide some of the signs of an infection. If you get an infection or suspect an infection during a course of treatment tell your doctor as soon as possible.

If you are a diabetic, your need for insulin or glucose lowering medicines may increase while being treated with SOLU-CORTEF.

Things to be careful of

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.

Be careful when driving or operating machinery until you know how SOLU-CORTEF affects you.

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

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 being treated with SOLU-CORTEF.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some side effects.

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

You may not experience any of them.

Ask your doctor or other health care professional to answer any questions you may have.

Children

Diluents that contain benzyl alcohol should not be used with SOLU-CORTEF to treat children.

Some diluents used with your medicine may contain the preservative benzyl alcohol. Benzyl alcohol has been associated with serious side effects in newborns (especially premature and low weight infants) which can be fatal.

Growth in children may be affected by treatment with SOLU-CORTEF

so your doctor may also monitor your child's height.

Tell your doctor or pharmacist 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
- 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 amount of urine, 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 muscles, muscle tenderness or weakness, not caused by exercise
- small lumps under the skin as a result of fat deposits in the tissues
- inflammation of the food pipe. You may experience difficulty or pain when swallowing, or heartburn problems with your growth

- hiccups
- 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 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 or problems with your reflexes (slow or too fast)
- 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 pressure. These could be symptoms of a rare tumour of the adrenal gland, which sits near the kidney.

Tell your doctor immediately or go to Emergency at your nearest hospital if you experience any of the following:

- 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
- vomiting blood or material that looks like coffee grounds, bleeding from the back passage, black sticky bowel motions (stools) 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.

These may be serious side effects. You may need urgent medical attention. Serious side effects are rare.

SOLU-CORTEF may 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 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-CORTEF.

It is very important to tell your doctor or pharmacist if you notice anything that is making you feel unwell.

After treatment with SOLU-CORTEF

Storage

SOLU-CORTEF will normally be stored in a hospital. The undiluted product should be stored below 25°C and should be protected from light (kept in the packaging before use).

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. Any solution not used within 24 hours should be discarded.

Product description

What SOLU-CORTEF looks like

SOLU-CORTEF powder for injection is a white, or nearly white powder in a vial. Vials are also available which have separate sections containing the powder and the liquid to dissolve the powder ready for injection (ACT-O-VIAL system).

SOLU-CORTEF 100 mg Plain Vial is supplied in packs of 5 vials. SOLU-CORTEF ACT-O-VIALS 100 mg, 250 mg and 500 mg are supplied in packs of 1 vial.

Identification

SOLU-CORTEF (hydrocortisone sodium succinate) can be identified by an Australian Register Number which is found on the carton.

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

500 mg: AUST R 167895.

Ingredients

SOLU-CORTEF contains hydrocortisone sodium succinate as the active ingredient.

Each vial also contains the following inactive ingredients:

- monobasic sodium phosphate monohydrate
- dibasic sodium phosphate.

The diluent for the ACT-O-VIALs consists of Water for Injections. It does not contain an antimicrobial preservative. Use in one patient on one occasion only.

Supplier

SOLU-CORTEF is supplied in Australia by:

Pfizer Australia Pty Ltd
Sydney NSW
Toll Free Number: 1800 675 229
www.pfizer.com.au

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