

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

Pr SOLU-CORTEF®

Hydrocortisone sodium succinate for injection

Read this carefully before you start taking **SOLU-CORTEF** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **SOLU-CORTEF**.

What is SOLU-CORTEF used for?

SOLU-CORTEF is used in adults and children:

- in the treatment of various conditions. These include allergy or inflammation;
- to replace corticosteroid hormone when the body does not produce enough. This is due to problems with the adrenal glands.
- in emergency treatment of certain conditions of shock or severe allergic reactions. SOLU-CORTEF is used when high blood levels of hydrocortisone are required quickly.

How does SOLU-CORTEF work?

SOLU-CORTEF contains corticosteroid hydrocortisone sodium succinate. Hydrocortisone belongs to a group of medicines called corticosteroids or steroids. Hydrocortisone is a hormone that decreases the body's immune response to certain diseases. This reduces symptoms such as swelling and redness.

What are the ingredients in SOLU-CORTEF?

Medicinal ingredients: Hydrocortisone sodium succinate

Non-medicinal ingredients:

Vial (powder): dibasic sodium phosphate dried and monobasic sodium phosphate anhydrous.

Vial (diluent): Sterile Water for Injection.

SOLU-CORTEF comes in the following dosage forms:

SOLU-CORTEF comes in a two-compartment Act-O-Vial system:

- upper compartment containing the sterile water (diluent)
- lower compartment containing the sterile white powder (drug): 100 mg, 250 mg, 500 mg and 1 g

Do not use SOLU-CORTEF if:

- you had an allergic reaction to hydrocortisone sodium succinate or any other corticosteroid medicine or any of the ingredients found in SOLU-CORTEF; or
- you have a fungal infection or any untreated infection.
- you have herpes simplex of the eye, except if SOLU-CORTEF is used only briefly for emergencies
- you have chickenpox or smallpox, except if SOLU-CORTEF is used only briefly for emergencies

- you have recently received a type of vaccine called a live or live / attenuated vaccine. Do not receive this vaccine during treatment with SOLU-CORTEF
- you have low platelet count and administer for intramuscular use

This medicine is not recommended for injection via the spinal cord (intrathecal or epidural)

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take SOLU-CORTEF. Talk about any health conditions or problems you may have, including if you:

- have or have had an infection (such as herpes simplex, chickenpox, tuberculosis, threadworm); **If you or your child is exposed to measles or chickenpox during treatment with SOLU-CORTEF, contact your healthcare professional immediately. Serious or fatal side effects can occur if you or your child have not already had these infections.**
- have recently had or are about to have any vaccination
- have bleeding problem; blood clotting problem
- have brittle bone (osteoporosis)
- have high blood pressure
- have water retention (oedema)
- have heart problems such as heart failure, heart disease or heart attack
- have kidney disease
- have diabetes
- have or have had seizures (convulsions) or other neurological problems
- have thyroid problem
- have muscle pain or weakness (such as myasthenia gravis)
- have certain eye diseases such as glaucoma, cataracts, herpes infection or any problems with the retina
- have liver disease such as cirrhosis
- have certain mental or mood conditions (such as depression)
- have or have had stomach or gut problems (ulcer, ulcerative colitis)
- have low potassium or calcium
- have a weak immune response. Tell your healthcare professional if you suspect an infection has occurred, as corticosteroids can make infections more likely and may mask their signs
- have Cushing's disease (caused by an excess of cortisol hormone)

Other warnings you should know about:

Serious Side Effects: SOLU-CORTEF can cause serious side effects, including:

- **skin cancer (Kaposi's sarcoma):** Kaposi's sarcoma have been reported with corticosteroid therapy, such as SOLU-CORTEF. Stopping treatment of SOLU-CORTEF may result in signs of the cancer going away.
- tumor of the adrenal glands (pheochromocytoma). This tumor has been reported with corticosteroid therapy, such as SOLU-CORTEF. Pheochromocytoma may cause death.
- fat deposition on or outside the lining of the spine (epidural lipomatosis). Taking corticosteroids in high doses for a long period of time can cause epidural lipomatosis.
- **Tumor lysis syndrome (TLS):** This is the sudden, rapid death of cancer cells due to treatment. TLS can cause life-threatening kidney failure and heart problems.

- **Suppression of hypothalamic pituitary-adrenal axis and Infections:** Solu-Cortef can make it hard for your body to respond to stress and illness. It can make you more likely to get infections and it can make infections that might be hidden in your body active again. You should avoid coming into contact with people who have measles or chicken pox while taking Solu-Cortef. If you are exposed, tell your healthcare professional right away.

See the **Serious side effects and what to do about them** table below for more information on these and other serious side effects.

Surgery: Before you have any operation, tell your doctor, dentist or anesthetist that you are taking SOLU-CORTEF.

Pregnancy and breastfeeding:

- If you are pregnant, or still able to get pregnant and/or breast-feed, there are specific risks you must discuss with your healthcare professional. Taking SOLU-CORTEF may:
 - slow the growth and cause low birth weight of the baby.
 - cause cataracts in babies. This risk is associated with mothers who take corticosteroids for a long period of time during pregnancy.
- If you are breastfeeding or planning to breastfeed, tell your healthcare professional.

Male fertility: Taking SOLU-CORTEF may affect male fertility.

Stopping treatment: If you suddenly stop taking SOLU-CORTEF, you may experience

- Serious adrenal insufficiency. Adrenal insufficiency is when the body does not make enough of the cortisol hormone. This may cause death.
- “Withdrawal syndrome”. This includes symptoms such as anorexia, nausea, vomiting, lack of energy, headache, fever, joint pain, peeling of skin, muscle pain, weight loss, and/or low blood pressure.

Immunosuppression:

- SOLU-CORTEF may:
 - hide symptoms of infection
 - reactivate dormant infections
 - cause infections due to lowered body resistance
- Tell your healthcare professional you are taking SOLU-CORTEF since it can affect the results of skin tests

Driving and Using Machines: SOLU-CORTEF may cause dizziness (vertigo), tiredness or blurred vision. Be careful about driving or doing activities that require you to be alert. If you experience these symptoms after taking SOLU-CORTEF, do NOT drive or operate machinery.

Children (less than 18 years of age):

- Children may experience a decrease in the speed of their growth. The healthcare provider will prescribe the lowest dose to minimize this risk.

- The healthcare professional will conduct frequent tests on the child if they are taking SOLU-CORTEF for a long period of time. Taking hydrocortisone for a long period of time increases the risk of developing a high intracranial pressure (growing pressure in skull).
- If hydrocortisone is given to a prematurely born baby, monitoring of the heart may be needed.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with SOLU-CORTEF:

- Medicines used to:
 - “thin” the blood (anticoagulants)
 - treat myasthenia gravis a muscle condition
 - treat bacterial infection (such as erythromycin, clarithromycin and troleandomycin)
 - treat fungal infections (such as ketoconazole and itraconazole)
 - treat inflammatory conditions (such as methylprednisolone)
 - treat epilepsy (such as barbiturates, carbamazepine, phenobarbital and phenytoin)
 - treat heart problems or high blood pressure (such as calcium channel blockers, diltiazem and digoxin)
 - treat high cholesterol (cholestyramine)
 - reduce extra fluid in the body (diuretics)
 - treat HIV infections (such as indinavir or ritonavir)
 - treat high blood sugar (diabetes)
 - treat tuberculosis (such as isoniazid, and rifampin)
 - to prevent or alleviate nausea and vomiting (such as aprepitant or fosaprepitant)
 - treat breast or ovarian cancer (aromatase inhibitors)
 - suppress or reduce the strength of the body's immune system (such as cyclosporine, cyclophosphamide, and tacrolimus which are used to help prevent organ rejection or treat cancer)
 - aspirin and non-steroidal anti-inflammatory drugs
 - vaccines
 - hormones (such as estrogen and somatropin)
 - potassium depleting agents

Do not drink grapefruit juice while taking Solu-Cortef.

How to take SOLU-CORTEF:

- SOLU-CORTEF will be given to you by your healthcare professional. They will decide to give SOLU-CORTEF to you by either:
 - into your vein (intravenous injection or infusion); or
 - into your muscle (intramuscular).
- Your healthcare professional will decide on the site of injection, as well as how much of the medicine and how many injections you will receive.
- SOLU-CORTEF should not be stopped abruptly. Do not stop taking SOLU-CORTEF without talking to your healthcare professional. You will need to come off this medicine slowly to avoid withdrawal symptoms.

- The healthcare professional will prescribe the lowest possible dose for the minimum period of time.

Usual dose:

- The dose depends on the:
 - type of condition being treated;
 - severity of the condition;
 - response to the treatment, and
 - your exposure to stress

Overdose:

If you think you, or a person you are caring for, have taken too much SOLU-CORTEF, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

If you are concerned that you, or a person you are caring for, may have missed a dose, talk to your healthcare professional immediately.

What are possible side effects from using SOLU-CORTEF?

These are not all the possible side effects you may have when taking SOLU-CORTEF. If you experience any side effects not listed here, tell your healthcare professional.

Potential side effects may include:

Skin problems:

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| <ul style="list-style-type: none"> • thin fragile skin • ecchymosis (spots caused by ruptured blood vessels) • petechiae (reddish spot containing blood that appears in skin) • stretch marks • dry, scaly skin • rash • redness • itching • hives • abscess | <ul style="list-style-type: none"> • moon face (enlargement of chin and forehead) • weight gain • abnormal fat deposits • hypopituitarism (a condition in which your pituitary gland fails to produce one or more of its hormones or does not produce enough of them). • Suppression of hypothalamic pituitary-adrenal axis (a condition that could lead to disabling the body's responses to physiological stress such as severe infections or trauma) • abnormal hair growth • thinning hair • acne • increased sweating • lightening or darkening of an area of skin |
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Hormone and metabolism problems:

- development of Cushingoid state (abnormal bodily condition caused by excess corticosteroids)

- thyroid gland problems

- sensation of tingling, tickling, prickling, or burning of a person's skin

Stomach and intestinal problems:

- nausea
- vomiting
- altered sense of taste (with rapid administration of large doses)
- abdominal pain
- bloating
- diarrhea
- indigestion
- increased appetite

Psychiatric problems:

- anxiety
- confusion
- hallucination
- emotional instability
- euphoria (intense feelings of well-being, elation, happiness, excitement and joy)
- mood swings
- personality changes
- drug dependence
- mania
- delusion
- schizophrenia
- abnormal behavior
- irritability

Musculoskeletal problems:

- loss of muscle mass
- muscle pain
- malaise (feeling of general discomfort or uneasiness)

Nervous system problems:

- headache
- dizziness
- amnesia
- vertigo
- impaired sensation, strength, and reflexes

Other:

- high cholesterol
- fatigue
- hiccups
- injection site reaction
- injection site scarring (dent/hole)

SOLU-CORTEF can cause abnormal blood test results. Your healthcare professional will do blood tests during your treatment

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
Heart failure: Shortness of breath, fatigue, weakness, dizziness, irregular heart beat			√
Blood clots: swelling, pain or tenderness, usually in the arm or leg		√	
Liver enlargement: jaundice (yellowing of the skin or whites of eyes), urine turns dark, nausea, vomiting, lower stomach pain		√	
Pancreatitis (inflammation of the pancreas): upper abdominal pain,		√	

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
fever, rapid heart beat, nausea, vomiting, tenderness when touching the abdomen			
Fluid retention, swelling		√	
High blood pressure: headaches or feeling unwell			√
Muscle weakness			√
Stomach ulcers (burst or bleeding ulcers): stomach pain, blood in stools and/or vomiting blood			√
Wounds that are slow to heal	√		
Convulsions			√
Psychological disorders: feeling depressed including thinking about suicide, feeling anxious, insomnia		√	
Irregular menstrual periods	√		
Diabetes: frequent urination, hunger and thirst		√	
Cramps and spasms		√	
Visual problems: failing eyesight, blurry vision, eye pain, increased pressure in your eyes		√	
Reactivation of tuberculosis: coughing blood or pain in the chest)			√
Infections: raised temperature and feeling unwell.			√
Osteoporosis (thin, fragile bones): bone/joint pain, broken bones, back pain that gets worse when standing or walking			√
Allergic reactions: rash, hives, swelling of the face, lips, tongue or throat. Difficulty swallowing or breathing			√
Suppression of hypothalamic pituitary-adrenal axis: dizziness, nausea, vomiting, abdominal pain, weakness, fatigue, generally feeling unwell, headache		√	

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to

interfere with your daily activities, tell your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

Before Reconstitution: Store SOLU-CORTEF at room temperature (15° C to 30°C).

After Reconstitution: Store reconstituted SOLU-CORTEF at room temperature (15° C to 30°C) and protect from light. Use solution only if it is clear. Discard unused solution after 3 days. Reconstituted SOLU-CORTEF can also be frozen for up to 1 month. Once thawed, the above guidelines should be followed for SOLU-CORTEF.

SOLU-CORTEF can be diluted for intravenous infusion. Unused diluted solution should be discarded after 4 hours.

After Dilution for Intravenous Infusion: Discard unused solution after 4 hours

Single use vial, discard after use.

Keep out of reach and sight of children.

If you want more information about SOLU-CORTEF:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the manufacturer's website <http://www.pfizer.ca>, or by calling 1-800-463-6001.

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