

## PATIENT MEDICATION INFORMATION

### READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

#### Pr **SOLU-CORTEF**<sup>®</sup>

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 caused by 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 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 h containing the sterile white powder (drug): 100 mg, 250 mg, 500 mg and 1 g

#### Do not use **SOLU-CORTEF** if:

- you are allergic to hydrocortisone sodium succinate, any other corticosteroid medicine, or any of the non-medicinal ingredients in **SOLU-CORTEF** (see **What are the ingredients in SOLU-CORTEF?**)
- 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 type of vaccine during treatment with SOLU-CORTEF.
- you have a low blood platelet count and SOLU-CORTEF is to be given as an injection into your muscle

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 problems or blood clotting problems
- have diabetes
- have brittle bones (osteoporosis)
- have high blood pressure
- have edema (water retention)
- have heart problems, such as heart failure, heart disease or have had a heart attack
- have kidney problems
- have or have had seizures (convulsions) or other neurological problems
- have thyroid problems
- have myasthenia gravis, a condition that causes progressive muscle pain and weakness
- have skin cancer (Kaposi's sarcoma), or a tumor of the adrenal glands (pheochromocytoma)
- have certain eye problems such as glaucoma, cataracts, herpes infection or any problems with the retina
- have liver disease, such as cirrhosis
- have mental health problems, such as depression
- have or have had stomach or gut problems, such as ulcers, ulcerative colitis
- have low levels of potassium or calcium in your blood
- have a weak immune response. Talk to 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 has been reported with the use of corticosteroids, such as SOLU-CORTEF. Stopping treatment with SOLU-CORTEF may result in signs of the cancer going away.
- **pheochromocytoma:** tumor of the adrenal glands. This tumor has been reported with the use of corticosteroids, such as SOLU-CORTEF. Pheochromocytoma may cause death.
- **epidural lipomatosis:** fat deposition on or outside the lining of the spine. Taking corticosteroids in high doses for a long period of time can cause epidural lipomatosis.

- **Tumor lysis syndrome (TLS):** 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, it can make infections that might be hidden in your body active again, and it can make existing infections worse. You should avoid coming into contact with people who have measles or chicken pox while taking SOLU-CORTEF. If you are exposed, talk to your healthcare professional right away.

**Surgery:** Before you have any operation, including dental surgery, tell your healthcare professional that you are taking SOLU-CORTEF.

**Pregnancy and breastfeeding:**

- If you are pregnant, or planning to become pregnant while being treated with SOLU-CORTEF, there are specific risks you must discuss with your healthcare professional.
- This medicine can cross the placenta and harm your baby.
- Tell your healthcare professional right away if you become pregnant while taking SOLU-CORTEF.
- If you are breastfeeding or planning to breastfeed, talk to your healthcare professional about the best way to feed your baby during treatment. SOLU-CORTEF can pass into your breast milk and harm your baby.

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

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

- **Adrenal insufficiency,** a condition where your body does not make enough of the cortisol hormone. This includes symptoms such as fainting, weakness, restlessness, nausea, vomiting, headache, dizziness, muscle weakness or joint pain and may cause death.
- **Withdrawal syndrome.** This includes symptoms such as decreased appetite, nausea, vomiting, lack of energy, headache, fever, joint pain, peeling of skin, muscle pain, weight loss, and low blood pressure or fainting.
- Tell your healthcare professional right away if you experience any of these symptoms after changing or stopping your treatment. Some of these symptoms can last for months after you stop taking SOLU-CORTEF.

**Immunosuppression:**

- SOLU-CORTEF may:
  - hide symptoms of infection
  - reactivate dormant infections
  - worsen existing infections
  - cause infections due to lowered body resistance

**Osteoporosis:** When using medicines like SOLU-CORTEF for long-term treatment, you may be at risk of:

- Breaking a bone (bone fractures)
- Weak bones (osteoporosis; increased risk of broken bones)

Take extra care to avoid any injury, especially falls.

**Blood Tests:** SOLU-CORTEF can cause abnormal blood test results. Your healthcare professional will decide when to perform blood tests and will interpret the results. If you are going to have a skin test for allergies, talk to your healthcare professional as SOLU-CORTEF may interfere with the results.

**Driving and Using Machines:** SOLU-CORTEF can cause dizziness, vertigo, tiredness or blurred vision. Give yourself time after taking SOLU-CORTEF to see how you feel before driving a vehicle or using machinery.

**Children (less than 18 years of age):**

- Corticosteroids can affect growth in children. Your healthcare professional will prescribe the lowest dose to minimize this risk.
- Your healthcare professional will regularly monitor growth and development in growing children.

**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 and prevent blood clots (such as warfarin, acenocoumarol, fluindione)
  - treat myasthenia gravis, a muscle condition (such as distigmine, neostigmine)
  - treat bacterial infections, called antibiotics (such as erythromycin, clarithromycin, rifampicin, rifabutin, troleandomycin)
  - treat fungal infections (such as ketoconazole, itraconazole, amphotericin-B)
  - treat inflammatory conditions (such as methylprednisolone)
  - treat epilepsy (such as barbiturates, carbamazepine, phenobarbital, phenytoin)
  - treat glaucoma
  - treat heart problems or high blood pressure (such as calcium channel blockers, digoxin, diltiazem and “water pills” or diuretics)
  - treat high cholesterol (cholestyramine)
  - treat HIV infections (such as indinavir, ritonavir)
  - treat diabetes
  - treat tuberculosis (such as isoniazid, rifampin)
  - to prevent or alleviate nausea and vomiting (such as aprepitant or fosaprepitant)
  - treat breast cancer (aromatase inhibitors)
  - suppress the immune system (such as cyclosporine, cyclophosphamide, tacrolimus)
  - relax you during surgery (such as pancuronium, vecuronium)
- acetylsalicylic acid and non-steroidal anti-inflammatory drugs (NSAIDs), used to treat fever and inflammation, such as ibuprofen
- medicines called anticholinesterases that can be used to treat Alzheimer’s Disease and other conditions
- vaccines
- hormones (such as estrogen and somatropin)
- grapefruit and grapefruit juice

**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.
- Your 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, regional poison control centre or Health Canada's toll-free number, 1-844 POISON-X (1-844-764-7669) immediately, even if there are no signs or 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.

Side effects may include:

##### **Skin problems:**

- 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

##### **Hormone and metabolism problems:**

- hypopituitarism (a condition in which your pituitary gland fails to produce one or more of its hormones or does not produce enough of them).
- thinning hair
- acne
- increased sweating
- lightening or darkening of an area of skin
- thyroid gland problems

Stomach and intestinal problems:

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

Musculoskeletal problems:

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

Nervous system problems:

- headache
- dizziness
- amnesia
- vertigo
- impaired sensation, strength, and reflexes
- sensation of tingling, tickling, prickling, or burning of a person's skin

Other:

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

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	
<b>Congestive heart failure</b> (heart does not pump blood as well as it should): shortness of breath, fatigue, weakness, dizziness, irregular heart beat, cough, swelling in the legs, ankles and feet			√
<b>Blood clots:</b> <b>In the leg or arm:</b> redness and swelling, pain or tenderness, skin that is warm to the touch <b>In the lung:</b> chest pain, usually worse with breathing, shortness of breath, cough that may contain blood, dizziness, loss of consciousness			√
<b>Liver problems:</b> yellowing of the skin or whites of eyes (jaundice), dark urine, pale stool, nausea, vomiting, upper abdominal pain		√	
<b>Pancreatitis</b> (inflammation of the pancreas): upper abdominal pain, fever, rapid heart beat, nausea,		√	

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	
vomiting, tenderness when touching the abdomen			
<b>Edema:</b> fluid retention, swelling of the hands, legs or feet		√	
<b>High blood pressure:</b> headaches, feeling unwell, shortness of breath			√
<b>Rhabdomyolysis</b> (breakdown of damaged muscle): Muscle weakness, muscle tenderness, muscle pain, dark urine, reduced urine output			√
<b>Stomach ulcers</b> (burst or bleeding ulcers): stomach pain, blood in stools and/or vomiting blood			√
<b>Seizures:</b> convulsions or fits with or without loss of consciousness			√
<b>Mental health problems:</b> feeling depressed including thinking about suicide, feeling anxious, insomnia, confusion, hallucinations (seeing or hearing things that are not really there), euphoria (intense feelings of well-being, elation, happiness, excitement and joy), mood swings, personality changes, memory problems		√	
<b>Hormonal changes:</b> irregular menstrual periods, abnormal hair growth	√		
<b>Diabetes:</b> frequent urination, hunger and thirst		√	
<b>Eye problems:</b> <b>Cataracts:</b> blurry vision, eye pain <b>Glaucoma:</b> increased pressure in your eyes, eye pain, halos around lights or coloured images, red eyes <b>Central serous chorioretinopathy (CSCR):</b> blurry vision or other changes in vision		√	
<b>Reactivation of tuberculosis:</b> coughing blood, pain in the chest, loss of appetite, unexplained			√

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	
weight loss, fever, chills, night sweats			
<b>Infections:</b> fever, chills, feeling unwell, sore throat, body aches, fatigue			√
<b>Osteoporosis</b> (thin, fragile bones): bone/joint pain, broken bones, back pain that gets worse when standing or walking			√
<b>Allergic reaction:</b> rash, hives, swelling of the face, lips, tongue or throat, difficulty swallowing or breathing, skin rash with swelling, itching and large welts, chest pain or tightness			√
<b>Suppression of hypothalamic pituitary-adrenal axis:</b> dizziness, nausea, vomiting, abdominal pain, weakness, fatigue, generally feeling unwell, headache		√	
<b>Cushing's syndrome</b> (high blood cortisol): round "moon" face, rapid weight gain especially around the body, excess sweating, thinning of the skin, easy bruising, dry skin, stretch marks, muscle weakness, fat deposits between the shoulder blades (buffalo hump), wounds that are slow to heal		√	
<b>Heart attack:</b> chest pain, pressure or discomfort, pain in the arm, shoulder, jaw, neck or back, shortness of breath, lightheadedness			√

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 ([canada.ca/drug-device-reporting](http://canada.ca/drug-device-reporting)) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

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

### Storage:

Your healthcare professional will store SOLU-CORTEF according to the product directions.

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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