

PART III: CONSUMER INFORMATION

PrSOLU-CORTEF® Act-O-Vials†
Hydrocortisone sodium succinate for injection

100 mg / 2mL water Act-O-Vials
250 mg / 2mL water Act-O-Vials
500 mg / 4mL water Act-O-Vials
1000 mg / 8mL water Act-O-Vials

This leaflet is Part III of a three-part “Product Monograph” published when SOLU-CORTEF was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about SOLU-CORTEF®. Contact your doctor or pharmacist if you have any questions about this drug.

ABOUT THIS MEDICATION

What the medication is used for:

SOLU-CORTEF is used

- in the treatment of various conditions such as allergy or inflammation;
- to replace corticosteroid hormone when the body does not produce enough due to problems with the adrenal glands.
- in emergency treatment of certain conditions of shock or severe allergic reactions, where high blood levels of hydrocortisone are required rapidly.

What it does:

SOLU-CORTEF contains a corticosteroid hormone. This hormone decreases the body’s immune response to certain diseases and reduces symptoms such as swelling and redness

When it should not be used:

Do not use SOLU-CORTEF if you have:

- had an allergic reaction to hydrocortisone or any other steroid medicine or any of the ingredients found in SOLU-CORTEF; or
- a fungal infection or any untreated infection.
- herpes simplex of the eye, except if SOLU-CORTEF is used only briefly for emergencies
- chickenpox or smallpox
- received a type of vaccine called a live or live / attenuated vaccine
- low platelet count

What the medicinal ingredient is:

Hydrocortisone sodium succinate.

What the nonmedicinal ingredients are:

Lower vial: dibasic sodium phosphate dried and monobasic sodium phosphate anhydrous.

Upper vial: Sterile Water for Injection.

What dosage forms it comes in:

SOLU-CORTEF comes in a two-compartment Act-O-Vial system: a clear vial containing sterile white powder (the drug) in the lower compartment and sterile water in the upper compartment. It is available in 4 strengths:

WARNINGS AND PRECAUTIONS

Before taking SOLU-CORTEF, talk to your doctor or pharmacist 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 doctor immediately.**
- you have recently had or are about to have any vaccination
- you have bleeding problem; blood clotting problem
- you have brittle bone (osteoporosis)
- you have high blood pressure
- you have heart problems such as heart failure
- you have kidney disease
- you have diabetes
- you have or have had seizures (convulsions) or other neurological problems
- you have thyroid problem
- you have muscle pain or weakness (such as myasthenia gravis)
- you have skin cancer (Kaposi’s sarcoma), or a tumor of the adrenal glands (pheochromocytoma)
- you have certain eye diseases such as glaucoma, cataracts, herpes infection or any problems with the retina
- you have liver disease such as cirrhosis
- you have certain mental or mood conditions (such as depression)
- you have or have had stomach or gut problems (ulcer, ulcerative colitis)
- you have low potassium or calcium
- you have a weak immune response
- you have Cushing’s disease (caused by an excess of cortisol hormone)
- you are pregnant or trying to become pregnant
- you are breast-feeding or planning to breast-feed

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

INTERACTIONS WITH THIS MEDICATION

Before taking SOLU-CORTEF, please talk to your doctor or pharmacist about all your other medications including those you bought without prescription, herbal or natural product and especially if are taking the following:

- drugs to treat glaucoma and epilepsy (such as acetazolamide)

- drugs to “thin” the blood (anticoagulants such as warfarin, coumadin)
- drugs to treat myasthenia gravis a muscle condition (such as distigmine and neostigmine)
- antibiotics (erythromycin, clarithromycin and troleandomycin, rifampicin and rifabutin)
- aspirin and non steroidal anti-inflammatory drugs (such as ibuprofen)
- drugs to treat inflammatory conditions (such as methylprednisolone)
- drugs to treat epilepsy (such as barbiturates and phenytoin)
- drugs for antifungal infections (such as ketoconazole)
- cyclosporine
- drugs for heart problems or high blood pressure (such as calcium channel blockers, diltiazem and digoxin)
- drugs to treat high cholesterol (cholestyramine)
- water pills (diuretics)
- drugs to treat HIV infections (such as indinavir or ritonavir)
- vaccines
- hormones, (such as estrogen and somatropin)
- drugs to treat diabetes
- drugs to treat tuberculosis
- drugs to prevent or alleviate nausea and vomiting (such as aprepitant or fosaprepitant)
- aromatase inhibitors (drugs to treat breast or ovarian cancer)
- immunosuppressants (drugs that suppress or reduce the strength of the body's immune system)
- potassium depleting agents

Do not drink grapefruit juice while taking Solu-Cortef.

PROPER USE OF THIS MEDICATION

DIRECTIONS FOR USING THE ACT-O-VIAL SYSTEM

1. Press down on plastic activator to force sterile water into the lower compartment.



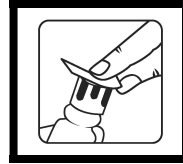
2. Gently agitate to effect solution.



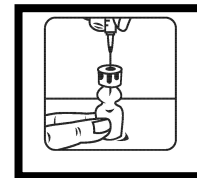
3. Remove plastic tab covering center of stopper.



4. Sterilize top of stopper with a suitable germicide.



5. Insert needle straight through center of stopper until tip is just visible.



6. Invert vial upside-down and withdraw dose.

Usual dose:

The initial dose of SOLU-CORTEF depends on the type of condition and the severity of the condition. Your doctor will decide on the site of injection, as well as how much of the medicine and how many injections you will receive.

A medical professional can also administer diluted SOLU-CORTEF as an intravenous infusion.

SOLU-CORTEF can affect growth in children so your doctor will prescribe the lowest dose that will be effective for your child.

When your condition has improved, your dose will be reduced gradually.

SOLU-CORTEF should not be stopped abruptly. Do not stop taking SOLU-CORTEF without talking to your doctor.

Overdose:

In case of drug overdose, contact your doctor, or a poison control centre, or go to emergency room of the hospital near you immediately, even if there are no symptoms

Missed Dose:

If you are concerned that you may have missed a dose, talk to you doctor or nurse immediately.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

The following is a list of side effects that may occur with SOLU-CORTEF. This is not a complete list. Therefore, check with your doctor immediately if you notice or are bothered by any unusual symptoms.

SOLU-CORTEF may hide symptoms of infections, may cause latent infections to become active, and may induce infections by normally inoffensive organisms due to lowered body resistance.

Potential side effects of SOLU-CORTEF include:

Allergic Reactions:

- anaphylaxis (a severe, life-threatening allergic reaction)
- cardiac arrest
- bronchospasm (narrowing of the airway)

Cardiovascular:

- heart failure
- heart attack
- arrhythmia (irregular heartbeat)
- high or low blood pressure
- blood clots
- thrombophlebitis (vein inflammation)
- thrombosis (blood clot within a blood vessel)
- high cholesterol
- Pediatric hypertrophic cardiomyopathy (thickening of heart muscle)

Dermatologic:

- thin fragile skin
- impaired wound healing
- swelling
- 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
- acne
- increased sweating
- lightening or darkening of an area of skin
- abscess
- suppressed reactions to skin tests
- thinning hair

Endocrine and Metabolism:

- development of Cushingoid state (abnormal bodily condition caused by excess corticosteroids)
- 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 growth in children
- abnormal hair growth
- new symptoms of diabetes
- thyroid gland problems

Gastrointestinal:

- stomach ulcer
- stomach bleeding
- inflammation of the pancreas and esophagus
- perforation of the bowel
- nausea
- vomiting or altered sense of taste (with rapid administration of large doses)
- abdominal pain
- bloating
- diarrhea
- indigestion
- bowel/bladder dysfunction
- increased appetite

Hepatic:

- enlarged liver

Pancreatic:

- Pancreatitis (inflammation of the pancreas)

Musculoskeletal:

- loss of muscle mass
- muscle weakness
- muscle pain
- malaise (feeling of general discomfort or uneasiness)
- osteoporosis
- pathological fractures
- vertebral compression fractures
- tendon rupture
- Charcot joint disease (neuropathic arthropathy)
- joint pain

Neurologic:

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

Ophthalmologic:

- cataracts
- increased intraocular pressure

- glaucoma

Psychiatric:

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

Sexual Function/Reproduction:

- menstrual irregularities
- increased or decreased motility and number of sperm

Hematology:

- above normal white blood cell count
- abnormal blood tests

Other:

- fatigue
- hiccups
- injection site reaction

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM			
Symptom / effect	Talk with your doctor or pharmacist		Stop taking drug and call your doctor or pharmacist
	Only if severe	In all cases	
Congestive heart failure			√
Fluid retention, swelling		√	
High blood pressure (symptoms of which are headaches or feeling unwell)			√

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Muscle weakness			√
Stomach ulcers (burst or bleeding ulcers; symptoms of which are 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 (symptoms of which can be frequent urination and thirst)		√	
Cramps and spasms		√	
Visual problems, failing eyesight		√	

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Symptom / effect	Talk with your doctor or pharmacist		Stop taking drug and call your doctor or pharmacist
	Only if severe	In all cases	
Reactivation of tuberculosis (symptoms of which could be coughing blood or pain in the chest)			√
Infections (symptoms might include a raised temperature and feeling unwell)			√
Bone/joint pain			√
Bone thinning			√
Allergic reactions in the form of angioedema (a severe skin reaction with swelling, itching and large welts).			√

This is not a complete list of side effects. For any unexpected effects while taking SOLU-CORTEF contact your doctor or pharmacist.

HOW TO STORE IT

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

After Reconstitution: Store reconstituted solution of SOLU-CORTEF at room temperature (15° C to 30°C). Protect from light. Discard unused solution after 3 days. Reconstituted SOLU-CORTEF can also be frozen for up to 1 month.

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.

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- Report online at <https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>
- Call toll-free at 1-866-234-2345
- Complete a Canada Vigilance Reporting Form and:
 - Fax toll-free to 1-866-678-6789, or
 - Mail to: **Canada Vigilance Program
Health Canada
Postal Locator 1908C
Ottawa, Ontario**

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at www.healthcanada.gc.ca/medeffect.

NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

This document plus the full product monograph, prepared for health professionals, can be found at: <http://www.pfizer.ca> or by contacting the sponsor, Pfizer Canada ULC, at: 1-800-463-6001.

This leaflet was prepared by Pfizer Canada ULC,

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