

## **PATIENT MEDICATION INFORMATION**

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

**PrCORTEF\***

#### **Hydrocortisone Tablets**

Read this carefully before you start taking **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 **CORTEF**.

#### **What is CORTEF used for?**

CORTEF is used in adults:

- to treat 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.

#### **How does CORTEF work?**

CORTEF is a corticosteroid hormone. It decreases the body's immune response to certain diseases and reduces symptoms such as swelling and redness.

#### **What are the ingredients in CORTEF?**

Medicinal ingredients: hydrocortisone

Non-medicinal ingredients: calcium stearate, cornstarch, lactose, mineral oil, sorbic acid, sodium and sucrose

#### **CORTEF comes in the following dosage forms:**

Tablets: 10 mg, 20 mg

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

- you are allergic to hydrocortisone, any other steroid medicine, or any of the non-medicinal ingredients in CORTEF (see **What are the ingredients in CORTEF?**)
- you have a fungal infection or any other untreated infection
- you have herpes simplex of the eye
- you have chickenpox or smallpox
- 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 CORTEF.

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

- are lactose intolerant or have one of the following rare hereditary diseases:
  - Galactose intolerance
  - Lapp lactase deficiency
  - Glucose-galactose malabsorption

Because lactose is a non-medicinal ingredient in CORTEF.

- have or have had an infection, such as herpes simplex, chicken pox, tuberculosis, threadworm. **If you or your child is exposed to measles or chickenpox during treatment with 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 heart problems, such as heart failure, heart disease or have had a heart attack
- have edema (water retention)
- 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:** 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 CORTEF. Stopping treatment with CORTEF may result in signs of the cancer going away.
- **pheochromocytoma:** tumor of the adrenal glands. This tumor has been reported with corticosteroid therapy, such as 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:** 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 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 CORTEF.

**Pregnancy and breastfeeding:**

- If you are pregnant, or planning to become pregnant while being treated with 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 CORTEF.
- If you are breastfeeding or planning to breastfeed, talk to your healthcare professional about the best way to feed your baby during treatment. CORTEF can pass into your breast milk and harm your baby.

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

**Stopping treatment:** If you suddenly stop taking 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, 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 CORTEF.

**Immunosuppression:**

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

**Osteoporosis:** When using medicines like 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:** 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 CORTEF may interfere with the results.

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

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

- Corticosteroid 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 CORTEF:**

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

**How to take CORTEF:**

- Take CORTEF exactly how your healthcare professional has told you.
- Do not stop taking CORTEF or change your dose without talking to your healthcare professional. Your healthcare professional will tell you how to reduce your dose gradually when you no longer need to take CORTEF.

**Usual dose:**

Your healthcare professional will decide on the dose that is right for you based on the condition you are being treated for.

**Overdose:**

If you think you, or a person you are caring for, have taken too much 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 miss a dose, take it as soon as possible. However, if it is almost time for your next dose, skip the missed dose and continue with your regular dosing schedule. Do not take a double dose to make up for a missed one.

**What are possible side effects from using CORTEF?**

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

Side effects may include:

- nausea, vomiting
- diarrhea
- indigestion
- altered sense of taste
- abdominal pain
- bloating
- increased appetite
- weight gain
- hiccups
- headache
- dizziness, spinning sensation (vertigo)
- fatigue
- muscle cramps, spasms and pain
- dark urine or reduced urine output
- rash
- redness, itching
- acne
- lightening or darkening of an area of skin
- thinning hair
- sensation of tingling, tickling, prickling, or burning in the hands or feet

<b>Serious side effects and what to do about them</b>			
<b>Symptom / effect</b>	<b>Talk to your healthcare professional</b>		<b>Stop taking drug and get immediate medical help</b>
	<b>Only if severe</b>	<b>In all cases</b>	
<b>Suppression of hypothalamic pituitary-adrenal axis:</b> dizziness, nausea, vomiting, 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	
weakness, fatigue, generally feeling unwell, headache			
<b>Allergic reaction:</b> rash, hives, itching, 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>Blood clots:</b> <b>In the leg or arm:</b> pain, redness and swelling, skin 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>Rhabdomyolysis</b> (breakdown of damaged muscle): Muscle weakness, muscle tenderness, muscle pain, dark urine, reduced urine output			√
<b>Osteoporosis</b> (thin, fragile bones): bone/joint pain, broken bones, back pain that gets worse when standing or walking			√
<b>Congestive heart failure</b> (heart does not pump blood as well as it should): shortness of breath with activity or when lying down, fatigue, weakness, dizziness, swelling in the legs, ankles and feet, rapid or irregular heartbeat, cough or wheezing			√
<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		√	

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>Diabetes:</b> frequent urination, hunger and thirst		√	
<b>Edema:</b> fluid retention, swelling of the hands, legs or feet		√	
<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>Heart attack:</b> chest pain, pressure or discomfort, pain in the arm, shoulder, jaw, neck or back, shortness of breath, lightheadedness			√
<b>High blood pressure:</b> headaches, feeling unwell, shortness of breath		√	
<b>Hormonal changes:</b> irregular menstrual periods, abnormal hair growth	√		
<b>Infections:</b> fever, chills, feeling unwell, sore throat, body aches, fatigue			√
<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>Reactivation of tuberculosis:</b> coughing blood, pain in the chest, loss of appetite, unexplained weight loss, fever, chills, night sweats			√
<b>Seizures:</b> convulsions or fits, with or without loss of consciousness			√

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>Stomach ulcers</b> (burst or bleeding ulcers): stomach pain, blood in stools and/or vomiting blood			√
<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, vomiting, tenderness when touching the abdomen		√	

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:

Store at room temperature (15°C to 30°C).

Keep out of the reach and sight of children.

#### If you want more information about 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-



3001.

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