

Hydrocortisone (Cortef®) 10 mg Tablet Shortage

SUPPLIERS OF HYDROCORTISONE ORAL TABLETS IN CANADA¹

Product	Strength	DIN	Manufacturer
Cortef®	10 mg	00030910	PFI
	20 mg	00030929	
	5 mg	Available only through the Special Access Programme for patients requiring low and/or precise doses.	

Health Canada approved indications of hydrocortisone oral tablets:

There are several indications for inflammatory, autoimmune and other conditions.² The focus of this document is conditions requiring corticosteroid replacement:

- primary or secondary adrenocortical insufficiency
- congenital adrenal hyperplasia

Background

- [Cortef®](#) 10 mg tablets are currently shorted.³
- For many indications in which corticosteroids are used, other corticosteroids may be used interchangeably.
- For adrenocortical insufficiency and congenital adrenal hyperplasia, hydrocortisone or cortisone are generally the preferred corticosteroids though other corticosteroids, especially prednisone, may be used.⁴⁻⁶
 - Because of the differences in mineralocorticoid activity of the different glucocorticoids, one cannot simply switch to a different glucocorticoid at the usual equivalent dose for patients requiring corticosteroid replacement. As such, **the goal is to keep patients on their original glucocorticoid.**⁴
- Currently there are no reports of Cortef® 20 mg tablet shortage⁷ though efforts must be made to protect this supply (see strategies below).

MESSAGE FROM THE CANADIAN SOCIETY OF ENDOCRINOLOGY AND METABOLISM:

Thousands of Canadians, adult and pediatric, use hydrocortisone (Cortef®) for treatment of adrenal insufficiency (e.g., Addison's Disease). For these patients, hydrocortisone is a critical, life-saving medication that must be taken every day. Missing this glucocorticoid medication can result in major health issues, hospitalizations and even death. Substitution with other medications can be very complicated and onerous, and in some patients may not work at all. Thus, the goal is to keep patient on their original glucocorticoid.

Conservation Strategies

- Patients should have adequate supply on hand at all times but **encourage to limit to no more than 30–60 days'** supply of any strength.
 - Should hydrocortisone 10 mg tablets be available in limited quantities:
 - Reserve for patients (especially young children) who require low doses in which 20 mg tablets are unsuitable.
 - Use 20 mg tablets for compounding oral suspensions.
 - Use 20 mg tablets instead of 2x10 mg tablets for **stress dosing** if appropriate.
 - A UK research group recommends the following at onset of signs and symptoms suggestive of COVID-19 (fever >38°C, a new or continuous dry cough, sore throat, loss of sense of smell or taste, aches and pains, fatigue)⁸:
 - adults and adolescents: 20 mg hydrocortisone orally every 6 hours
 - children: triple the usual daily dose and administer in four equal doses every 6 hours
- **Note:** patients should follow the stress dose guidelines prescribed to them, which may differ from the above.

Pharmaceutical Alternatives

• Cortef® 5 mg Tablets

- Available through the Special Access Programme for patients requiring low doses.⁹
- Only prescribers may apply on behalf of the patient. Application information [here](#).
- Some hospital pharmacies are able to help facilitate applications.

• Cortef® 20 mg Tablets

- Cortef® 20 mg tablets are not scored; the manufacturer has no stability studies on the use of cut 20 mg tablets and cannot recommend this practice. However, when necessary, consider splitting 20 mg tablets so long as¹⁰⁻¹²:
 - The patient's dose is stable.
 - This is under ideal conditions; using cut 20 mg tablets is preferable to switching to a different glucocorticoid even if dose has not been stabilized.
 - The patient/caregiver has necessary physical (e.g. dexterity, vision, strength) and cognitive abilities and is motivated to split tablets. If not, consider compounded suspension using 20 mg tablets.
 - A tablet-splitting device is used.
 - One tablet is split at a time; each half is taken before splitting the next tablet.
 - The dose in each half may not be uniform, which will be evened out by taking both halves of the same tablet.
 - Splitting one tablet at a time considerably reduces exposure time of split tablets to air and moisture that may reduce stability over longer periods.
 - The patient is monitored for therapeutic effect.

Other Important Information

- Ensure patients always have an [emergency injection kit](#) on hand, know how to use it and have an emergency care [plan](#).
 - Ensure patients and caregivers have been given training on intramuscular/subcutaneous administration (see resources below).
 - Patients may want to have a [notice](#) available to provide to emergency personnel.
- Encourage patients to have an emergency card, bracelet or necklace stating the diagnosis and/or that in an emergency, intravenous hydrocortisone (e.g., Solu-Cortef®) is required.
 - Acceptable formulations are hydrocortisone sodium succinate and hydrocortisone sodium phosphate (sodium phosphate formulation is not available in Canada).
 - Hydrocortisone acetate (not available in Canada in injectable form) is a slow-onset product and is not suitable for emergency use.¹³
- Be alert to the possibility that emergency attention may be required when communicating with patients or their caregivers.
 - Some of the signs and symptoms that may be apparent in adrenal crisis may include¹⁴:
 - vomiting, diarrhea, headache, dizziness, low back pain, low blood pressure, shock-like symptoms, confusion, low blood sugar, loss of appetite
- Stress to patients the importance of continuing corticosteroid therapy unless directed otherwise by their medical professional.
- Remind patients to keep a [list of current medications](#), ensure they [understand their medications](#) and are taking correctly – especially to double check the tablet strength before taking if more than one strength is on hand. Report medication incidents to [ISMP Canada](#)
- Corticosteroids are often recommended to be taken with food¹⁵ though this is not always necessary for patients requiring replacement corticosteroids and may delay absorption.
 - Studies assessing the effects of food on time to peak concentration of oral hydrocortisone have found variable results.¹⁶⁻¹⁸ However:
 - Doses used for physiological replacement are unlikely to cause gastrointestinal distress.
 - Patients may notice quicker onset if hydrocortisone tablets are taken in the fasted state.
- Patients with adrenal insufficiency may be at higher risk of contracting infections, including COVID-19.⁹ It is important that [measures](#) – as recommended for the general population - are taken to prevent infection.
 - In the event of COVID-19 infection it is of even greater importance to ensure:
 - daily corticosteroid replacement, or
 - the more likely scenario of stress glucocorticoid dosing during symptomatic illness, and
 - emergency use of parenteral hydrocortisone for those with suspected adrenal crisis

- Emergency resources for patients with adrenal insufficiency:
 - [Emergency card](#)
 - Emergency injection instructions [wallet card](#)
 - Emergency Injection instructions [video](#)
 - Emergency injection instructions [written/infographic](#)
- More information is available at:
 - [Canadian Addison Society](#)
 - [Canadian Society of Endocrinology and Metabolism](#)
 - [Society for Endocrinology](#) – document regarding COVID-19 for patients taking replacement steroids

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Prepared by medSask

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