



06 June 2022

Importation of US-labelled CORTEF 10 mg Tablet due to Shortage of Canadian-labelled CORTEF 10 mg Tablet

To: Healthcare Professionals

Key Messages

- There is a critical shortage of CORTEF (Hydrocortisone Tablets, 10 mg) in Canada. In order to mitigate the current market shortage, Health Canada has permitted the exceptional, temporary importation and sale of US-labelled CORTEF, by Pfizer Canada ULC and has added this product to the List of Drugs for Exceptional Importation and Sale (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-shortages/list.html>).
- In Canada, CORTEF is a prescription product indicated for endocrine disorders, rheumatic disorders, collagen diseases, dermatologic diseases, allergic states, ophthalmic diseases, respiratory diseases, hematologic disorders, neoplastic diseases, edematous states, gastrointestinal diseases, and various other pathologies.
- The US-labelled product has the **same strength, dosage form, and route of administration** as the Canadian-authorized product, but the products **differ with respect to the packaging**.
- **Healthcare professionals should refer to the Canadian Product Monograph for CORTEF available in English and French on the Health Canada Drug Product Database (<https://health-products.canada.ca/dpd-bdpp/index-eng.jsp>) for information on appropriate use including the indications, contraindications, dosage and administration, warnings and precautions, adverse reactions, drug interactions, and storage conditions.**

Information on the Imported Product

Product Name	Description	Country of Origin and Identifying Code	Importer in Canada
CORTEF	10 mg hydrocortisone tablet For oral administration. Available in plastic bottles of 100 tablets.	United States National Drug Code (NDC) 0009-0031-01	Pfizer Canada ULC

To mitigate the current shortage, a limited quantity of US-labelled CORTEF will be made available to the Canadian market. Pfizer is making every effort to expedite the resupply of the Canadian-authorized CORTEF.

The differences in packaging between the US-labelled and Canadian-authorized products are bolded in the table below:

Packaging of the US-labelled CORTEF	Packaging of the Canadian-authorized CORTEF
60 mL white plastic bottle with a white squeeze and turn cap	40 mL amber glass round bottle with a white seal cap

Information about US-labelled CORTEF for healthcare professionals is available for reference in English and can be found in the FDA-approved US Prescribing Information (USPI) at: [Cortef Label \(fda.gov\)](https://www.fda.gov/oc/ohrt/cortef-label) and attached to the side of each US bottle. Images of the US-labelled product can be found in the Appendix below.



Healthcare professionals are advised that aspects of the US bottle label may differ from the Canadian-authorized product. **Proper selection of the intended product must be confirmed to avoid confusion with other products and prevent medication errors.**

The US-labelled product does not have a Drug Identification Number or a barcode that scans in medication management systems in Canada. A facility-generated sticker may be required to enable barcode scanning and allow proper identification of the product being dispensed and administered. The bottle labels of the US-labelled product are in English only


Reporting Adverse Drug Reactions

Adverse drug reactions associated with the use of CORTEF 10 mg should be reported to Pfizer Canada ULC at 1-866-723-7111 or by fax at 1-855-242-5652 or to Health Canada at <https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html> or by calling toll-free at 1-866-234-2345.

Questions or Concerns

For medical related queries, please contact our Pfizer Canada ULC Medical Information Group at 1-800-463-6001. For all other queries, please contact our Customer Service Group at 1-800-387-4974.

Sincerely,

DocuSigned by:

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Vratislav Hadrava M.D., Ph.D.
Vice-President and Medical Director
Pfizer Canada ULC



Appendix

Image of the US-labelled CORTEF

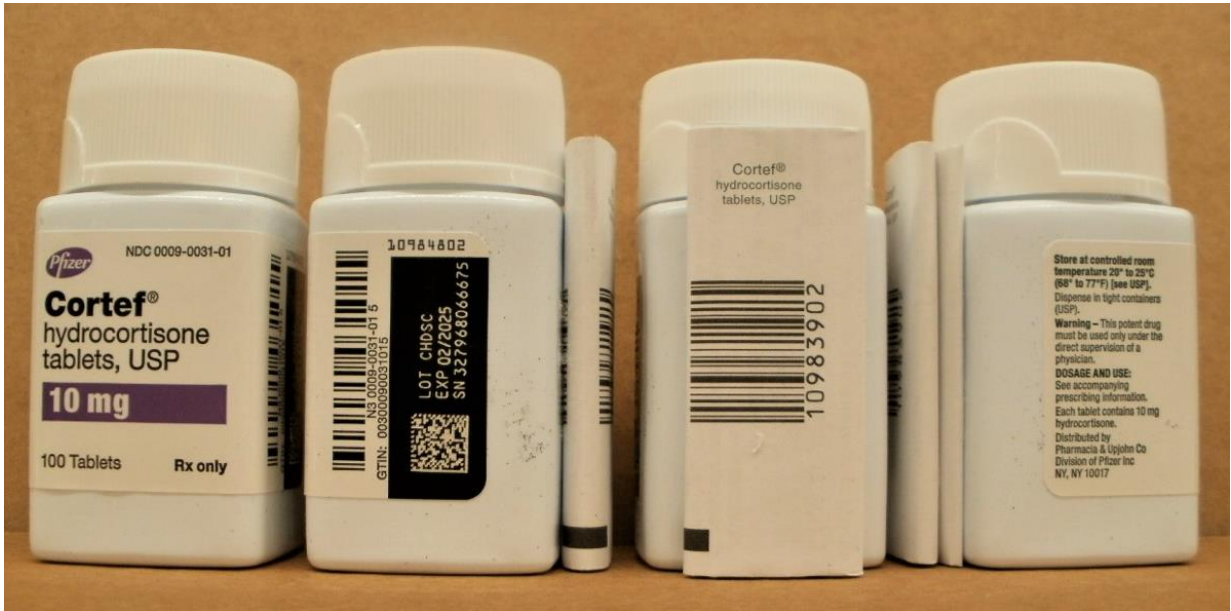


Image of the US Bottle Label

