

## Drug Shortages: Carbamazepine Extended-Release Tablets

Health Canada has approved the temporary importation of a limited supply of US-labelled carbamazepine extended-release tablets by Septa Pharmaceuticals to help alleviate the current shortage of this product. US-labelled carbamazepine extended-release tablets can be used in a comparable way to the approved Canadian product (i.e., has the same active ingredient, strength and dosage form as the current products approved by Health Canada).

Effective June 20, 2024, the US-labelled carbamazepine extended-release tablets will be listed temporarily as a **non-interchangeable full Formulary benefit** with the currently listed products on the Saskatchewan Formulary.

PseudoDIN	Strength	Product Name	Dosage Form
09858341	200mg	Septa Pharmaceuticals US-labelled Carbamazepine	Extended-Release Tablets
09858342	400mg	Septa Pharmaceuticals US-labelled Carbamazepine	Extended-Release Tablets

The US-labelled carbamazepine extended-release tablets differs from the Canadian marketed product in the following aspects:

- The US-labelled product has a different formulation than the Canadian-authorized product and as a result, its bioequivalence to the Canadian-authorized product has not been confirmed. **Health Canada recommends enhanced monitoring of patients taking the imported drug.** Carbamazepine has a narrow therapeutic index, and interchanging between non-bioequivalent products with a narrow therapeutic index may result in patients receiving minor variations in drug concentration, which may alter the effectiveness and/or safety of the drug.
- US products also differ from the Canadian-market versions in their labelling (English-only), physical appearance, and non-medicinal ingredients.

Information about the carbamazepine extended release tablets for healthcare professionals is available on the following website: <https://recalls-rappels.canada.ca/en/alert-recall/importation-usa-authorized-carbamazepine-extended-release-tablets-usp-200-mg-and-400>

**What will individuals pay for the of US-labelled carbamazepine extended-release tablets?** Individuals will pay according to their usual coverage, deductible and/or copayment.

**Can I dispense the of US-labelled carbamazepine extended-release tablets instead of the existing products listed on the Formulary?** *Pharmacies should continue to dispense the approved Health Canada products listed on the Saskatchewan Formulary if it is available.* However, if the Canadian product is not available, Health Canada has temporarily approved the of US-labelled carbamazepine extended-release tablets for use in Canada.

- If the prescription authorizes the dispensing of a particular strength and dosage of carbamazepine extended-release tablets without specifying a specific brand or product name, then a pharmacist may dispense the US-labelled carbamazepine extended-release tablets.
- Because this product is non-interchangeable, if a prescription directs the dispensing of specific brand of carbamazepine extended-release tablets (e.g., Tegretol CR®), a new prescription would be required to dispense the US-labelled carbamazepine extended-release tablets.

**Who to Call:** If you have any questions or issues with submitting claims for adjudication, call:

- DPEBB at 306-787-3317 (Regina) or 1-800-667-7581