

## Importation of United States-authorized Carbamazepine extended-release tablet due to shortage of Canadian-authorized Carbamazepine extended-release tablet

Due to the shortage of carbamazepine extended-release tablets in Canada, Health Canada has allowed the temporary importation by Septa Pharmaceuticals Inc. of Ingenus Pharmaceuticals LLC, US-authorized (US) Carbamazepine 200 mg and 400 mg extended-release tablets, USP from the United States with English-only labels.

This medication has been added to Health Canada's List of Drugs for Exceptional Importation and Sale in Canada.

**Temporary Product Identification Numbers (PINs) have been assigned to these products effective as of June 13, 2024. This product will be available for direct order from Septa and various distributors in Alberta.**

PIN	Product description
09858341	(US) Carbamazepine 200 mg extended-release tablet
09858342	(US) Carbamazepine 400 mg extended-release tablet

Additional information for pharmacists and other health care providers:

- The USA-authorized product can be used in the same manner as the Canadian-authorized product. Refer to the Canadian Product Monograph for Tegretol CR (carbamazepine extended-release tablets) 200 mg and 400 mg from Novartis Pharmaceuticals Canada Inc., available in English and French on Health Canada's Drug Product Database.
- The US-labelled product has the **same** active ingredient, strength, dosage form and route of administration as the Canadian-authorized products. **However, the US-authorized product has a different formulation and different physical appearance than the Canadian-authorized product and bioequivalence with the Canadian-authorized product has not been confirmed.**
- **Carbamazepine is considered to have a narrow therapeutic index, exhibiting a narrow difference between therapeutic and toxic plasma concentrations. In general, interchanging between non-bioequivalent products that have a narrow therapeutic index may result in patients being exposed to minor variations in drug concentrations, which may affect the effectiveness or the safety of the drug. Enhanced monitoring for the imported drug for the intended disease condition is recommended.**

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Please see the following comparison chart for ways the products **differ**:

	<b>US-authorized product</b>	<b>Canadian-authorized product</b>
200 mg	Tablets are white in colour, round in shape and 10 mm in size, without score, with the imprint code I258.	Tablets are beige-orange, oval and slightly biconvex. C/G engraved on one side and H/C engraved on the other. Fully bisected on both the sides.
400 mg	Tablets are white in colour, round in shape and 12 mm in size, without score, with the imprint code I259.	Tablet is brown-orange, oval and slightly biconvex. CG/CG engraved on one side and ENE/ENE engraved on the other. Fully bisected on both the sides.

- US-authorized Carbamazepine extended-release tablets, USP must be swallowed whole and never crushed or chewed.
- Aspects of the label on the bottle of the US-authorized product may differ from the Canadian-authorized product. Proper selection of the intended product must be verified to avoid confusion with other products and to prevent medication errors.
- Information about USA-authorized Carbamazepine extended-release tablets, USP 200 mg and 400 mg for reference by health care professionals is available (in English only) at <https://dailymed.nlm.nih.gov/dailymed/druginfo.cfm?setid=de67de85-15b3-4c27-b604-d028ce3789d0>.
- For additional information on this shortage please refer to the following link <https://recalls-rappels.canada.ca/en/alert-recall/importation-usa-authorized-carbamazepine-extended-release-tablets-usp-200-mg-and-400>.

**Temporary Benefit added to the Alberta Drug Benefit List (ADBL)**

To ensure coverage is provided for these products, for members of eligible government-sponsored drug programs, the below products will be considered as temporary benefits for the ADBL.

As of **June 13, 2024**, all claims for these products will be adjudicated to the price indicated per tablet.

<b>PIN</b>	<b>Product description</b>	<b>Price per tablet</b>
09858341	(US) Carbamazepine 200 mg extended-release tablet	<b>\$4.7080</b>
09858342	(US) Carbamazepine 400 mg extended-release tablet	<b>\$5.2210</b>

Alberta Blue Cross will continue to monitor the availability of shorted products and potential alternatives, in addition to working with other provinces and territories, manufacturers and Health Canada to address this shortage and minimize the impact on Albertans.

For assistance with benefit or claim inquiries, please contact an Alberta Blue Cross Pharmacy Services Provider Relations contact centre representative at

780-498-8370 (Edmonton and area)  
 403-294-4041 (Calgary and area)  
 1-800-361-9632 (toll free)  
 FAX 780-498-8406 (Edmonton and area)  
 FAX 1-877-305-9911 (toll free)

Alberta Blue Cross offers online access to current Pharmacy Benefacts and supplemental claiming information to assist with the submission of your direct bill drug claims.

Visit [ab.bluecross.ca/providers/pharmacy-home.php](http://ab.bluecross.ca/providers/pharmacy-home.php)

