

Importation of United States-labelled colesevelam hydrochloride due to shortage of Canadian-labelled colesevelam hydrochloride

Due to the shortage of colesevelam hydrochloride in Canada, Health Canada has allowed the temporary importation of Glenmark Pharmaceuticals Canada’s US-labelled (US) Colesevelam 625 mg Tablet from the United States.

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

A temporary Product Identification Number has been assigned to this (US) Colesevelam 625 mg Tablet (PIN 09858334) effective as of April 10, 2024.

In Canada, colesevelam hydrochloride tablets are indicated for the reduction of cholesterol blood level in patients with hypercholesterolemia (Fredrickson Type IIa) as an adjunct to diet and lifestyle changes, when the response to these measures has been inadequate and in patients who are not adequately controlled with an HMG-CoA reductase inhibitor (statin) alone or who are unable to tolerate a statin.

The US-labelled product has the **same** active ingredient, strength, dosage form, route of administration, product formulation, indications, dosage and administration instructions as the Canadian-authorized products.

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

	Lodalís (DIN 02373955)	Apo-Colesevelam (DIN 02494051)	(US) Colesevelam (PIN 09858334)
Tablet description as per the authorized product labelling	Off-white, capsule-shaped, film-coated tablets imprinted with “LODALIS” on one side.	White to off-white, oval, biconvex coated tablet. Engraved “APO” on one side and “C625” on the other side.	Off-white to pale yellow, capsule shaped, biconvex film-coated tablets imprinted with “G433” on one side and plain on the other side.
Non-medicinal ingredients as per the authorized product labelling	Microcrystalline cellulose, colloidal anhydrous silica, magnesium stearate, water, hypromellose, diacetylated monoglycerides, iron oxide black, propylene glycol.	Magnesium stearate, microcrystalline cellulose, silicon dioxide, diacetylated monoglycerides, Hypromellose.	Microcrystalline cellulose, colloidal anhydrous silica, magnesium stearate, water, hypromellose, diacetylated monoglycerides, iron oxide black, propylene glycol, pregelatinized starch, methylene chloride.

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	Lodalis (DIN 02373955)	Apo-Colesevelam (DIN 02494051)	(US) Colesevelam (PIN 09858334)
Storage condition as per the authorized product labelling	Store at room temperature 15 to 30° C. Protect from moisture.	Store at room temperature 15 to 30° C. Protect from moisture.	Store at 20°C to 25°C (68°F to 77°F); excursions permitted to 15°C to 30°C (59°F to 86°F) [see USP Controlled Room Temperature]. Protect from moisture and store in a dry place. Keep tablets in original/ pharmacy container.

Health care professionals are advised that aspects of the outer labels and packaging of the US-labelled product may differ from marketed colesevelam hydrochloride 625 mg tablets in Canada.

Proper selection of the intended product must be verified to avoid confusion with other products and prevent medication errors.

Information about US-labelled colesevelam hydrochloride 625 mg tablets for health care professionals is available for reference in English at www.glenmarkpharma-us.com.

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

To ensure coverage is provided for this product, for members of eligible government-sponsored drug programs, the **(US) Colesevelam 625 mg Tablet (PIN 09858334)** will be considered as a temporary benefit for the *ADBL*.

As of **April 10, 2024**, all claims for this product will be adjudicated to the price of **\$0.8896** per tablet.

Alberta Blue Cross will continue to monitor the availability of shorted product(s) 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

