

Welchol[®] (colesevelam) – New formulation approval

- On April 3, 2019, the [FDA approved](#) Daiichi Sankyo's [Welchol \(colesevelam\)](#) chewable bars, as an adjunct to diet and exercise to reduce elevated low-density lipoprotein cholesterol (LDL-C) in adults with primary hyperlipidemia and as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.
 - Welchol is indicated to reduce LDL-C levels in boys and postmenarchal girls, 10 to 17 years of age, with heterozygous familial hypercholesterolemia who are unable to reach LDL-C target levels despite an adequate trial of dietary therapy and lifestyle modification.
 - Welchol should not be used for the treatment of type 1 diabetes or for the treatment of diabetic ketoacidosis.
 - The effect of Welchol on cardiovascular morbidity and mortality has not been determined.
 - Welchol has not been studied in type 2 diabetes in combination with a dipeptidyl peptidase 4 inhibitor.
 - Welchol has not been studied in Fredrickson Type I, III, IV, and V dyslipidemias.
 - Welchol has not been studied in children younger than 10 years of age or in premenarchal girls.
- The approval of Welchol chewable bars was based on studies conducted with Welchol tablets.
- Welchol is contraindicated in patients with:
 - Serum TG concentrations > 500 mg/dL
 - History of hypertriglyceridemia-induced pancreatitis
 - A history of bowel obstruction
- Warnings and precautions of Welchol include hypertriglyceridemia and pancreatitis, gastrointestinal obstruction, vitamin K or fat-soluble vitamin deficiencies, drug interactions, risks in patients with phenylketonuria, and macrovascular outcomes.
- The most common adverse reactions ($\geq 2\%$ and greater than placebo) with Welchol use were constipation, dyspepsia, and nausea.
- The recommended dosage of Welchol is 3.75 grams (one chewable bar) daily, with a meal. Welchol chewable bars contain approximately 80 calories per bar.
- Daiichi Sankyo's launch plans for Welchol chewable bars are pending. Welchol chewable bars will be available in a 3.75 gram strength (chocolate, strawberry, and caramel flavors).