

## Welchol® (colesevelam HCl) Fact Sheet

- **Welchol**® (colesevelam HCl) along with diet and exercise is the only FDA-approved medicine with a single active ingredient proven to lower both A1C and LDL or "bad" cholesterol in adults with type 2 diabetes and/or high cholesterol.
  - Welchol should not be used to treat type 1 diabetes or diabetic ketoacidosis. Welchol has not been studied with all anti-diabetic medications. Welchol has not been studied in children younger than 10 years old or in girls who have not had a menstrual period.
- In May 2000, the U.S. Food and Drug Administration (FDA) granted marketing approval for **Welchol** as an adjunct to diet and exercise for the reduction of elevated LDL cholesterol in adult patients with primary hyperlipidemia (Fredrickson Type IIa) as monotherapy or in combination with a hydroxymethyl-glutaryl-coenzyme A (HMG CoA) reductase inhibitor (a statin).
- In January 2008, **Welchol** was approved by the FDA as an adjunct to diet and exercise to improve glycemic control (measured as hemoglobin A1C) in adults with type 2 diabetes mellitus in combination with metformin, sulfonylureas, and/or insulin.
- In October 2009, **Welchol** was approved by the FDA as an adjunct to diet and exercise for the reduction of elevated LDL cholesterol in boys and postmenarchal girls 10 to 17 years of age with heterozygous familial hypercholesterolemia (a genetic disorder that causes high cholesterol) alone or in combination with a statin after failing an adequate trial of diet therapy.
- **Welchol** is marketed by Daiichi Sankyo, Inc.

### Mechanism of Action

- **Welchol** is a bile acid sequestrant that lowers "bad" cholesterol differently from statins. While statins work in the liver, **Welchol** works in the intestines. Bile acids are needed to help digest fat from foods that are eaten. **Welchol** attaches to these bile acids and removes some of them from the body. When levels of bile acids are reduced, the liver needs to make more and takes cholesterol from the bloodstream to do so, thereby lowering "bad" cholesterol.
- It is not known exactly how **Welchol** lowers A1C, but studies have shown that, when added to metformin, sulfonylureas, or insulin therapy, **Welchol** helped to significantly lower A1C levels in adults with type 2 diabetes.

### Clinical Data: LDL Cholesterol Lowering in Patients with High Cholesterol

- In two different studies, when added to 10 mg each of simvastatin or atorvastatin, **Welchol** lowered "bad" cholesterol by 42 percent and 48 percent, respectively. Patients did not have to have type 2 diabetes in these two studies. The most common adverse events seen in these studies were flatulence and constipation.<sup>1,2</sup>

- In a clinical study of boys and postmenarchal girls 10 to 17 years of age with heterozygous familial hypercholesterolemia, **Welchol** as monotherapy or in combination with a statin reduced total mean LDL cholesterol by 13 percent. The most common adverse events seen in this study included nasopharyngitis, headache, fatigue, creatine phosphokinase increase, rhinitis and vomiting.

#### **Clinical Data: A1C and LDL Cholesterol Lowering in Patients with Type 2 Diabetes**

- **Welchol** has been shown to give adult patients significant A1C reductions when added to preexisting metformin, insulin, or sulfonylurea therapies.
- In these same studies, **Welchol** demonstrated significant reductions in LDL cholesterol levels.
- The most common adverse events seen in these studies was constipation, inflamed nasal passages and throat, indigestion, and low blood sugar. **Welchol** was not associated with weight gain and incidence of low blood sugar was comparable to placebo. **Welchol** may increase the exposure of co-administered metformin extended release (ER). Patients taking concomitant metformin ER and **Welchol** should closely monitor their blood sugar levels.
- **Welchol** has not been shown to prevent heart disease or heart attacks.

#### **Dose Strength**

- **Welchol** (colesevelam HCl) is available in two formulations – **Welchol Tablets** and **Welchol for Oral Suspension**.
- **Welchol Tablets** are available as 625 mg tablets. The recommended dose of **Welchol Tablets** is six tablets once daily or three tablets twice daily. **Welchol Tablets** should be taken with a meal and liquid. Because of tablet size, **Welchol Tablets** should be used with caution in patients who have difficulty swallowing or swallowing disorders.
- **Welchol for Oral Suspension** is sugar-free and available in 3.75 gram single-dose packets. The recommended dose of **Welchol for Oral Suspension** is one 3.75 gram packet once daily, which can be mixed with water, diet soft drinks or fruit juice. It is important for phenylketonurics to know that **Welchol for Oral Suspension** contains 27 mg phenylalanine per 3.75 gram dose. **Welchol for Oral Suspension** should not be taken in its dry form.
- It is recommended that pediatric patients with heterozygous familial hypercholesterolemia use **Welchol for Oral Suspension**. It is also recommended that any patient who has difficulty swallowing tablets use **Welchol for Oral Suspension**.

<sup>1</sup> Knapp, HH, et al. Efficacy and safety of combination simvastatin and colesvelam in patients with primary hypercholesterolemia. *The American Journal of Medicine*. 2011; 110: 352-359.

<sup>2</sup> Hunninghake, et al. Coadministration of colesevelam hydrochloride with atorvastatin lowers LDL cholesterol additively. *Atherosclerosis*. 2001; 158:407-416.

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#### **What is Welchol (colesevelam HCl)?**

**Welchol**, along with diet and exercise, lowers LDL or “bad” cholesterol. It can be taken alone or with other cholesterol-lowering medications known as statins.

Welchol lowers LDL cholesterol in boys, and in girls who have had a menstrual period, ages 10 to 17 years, with a condition known as heterozygous familial hypercholesterolemia (a genetic disorder that causes high cholesterol) alone or with other cholesterol-lowering medications known as statins after inadequate control with diet alone.

Welchol, along with diet and exercise, also lowers blood sugar levels in adult patients with type 2 diabetes mellitus when added to other anti-diabetes medications (metformin, sulfonylureas, or insulin).

Welchol should not be used to treat type 1 diabetes or diabetic ketoacidosis.

Welchol has not been studied with all anti-diabetes medications.

Welchol has not been studied in children younger than 10 years old or in girls who have not had a menstrual period.

### **Important Safety Information About Welchol (colesevelam HCl)**

Welchol is available by prescription only. Ask your HCP if Welchol is right for you.

Welchol is not for everyone, especially those with:

- a history of intestinal blockage,
- blood triglyceride levels of greater than 500 mg/dL, or
- a history of pancreatitis (inflammation of the pancreas) due to high triglyceride levels.

Welchol has not been shown to prevent heart disease or heart attacks.

Tell your health care provider (HCP) if you have high triglycerides (greater than 300 mg/dL).

Tell your HCP if you have stomach or intestinal problems, including gastroparesis (when the stomach takes too long to empty its contents), abnormal contractions of the digestive system, a history of major gastrointestinal tract surgery, if you have trouble swallowing, or if you have vitamin A, D, E, or K deficiencies.

Welchol has known interactions with cyclosporine, glimepiride, glipizide, glyburide, levothyroxine, certain birth control pills, olmesartan medoxomil, and metformin extended release (ER). Welchol has not been studied with all combinations of drugs and supplements. Please tell your HCP about all medications and supplements you may be taking before beginning Welchol, as your HCP may tell you to take your other medications and supplements 4 hours before taking Welchol.

Remember to tell your HCP if you are pregnant, plan to become pregnant, or are breastfeeding.

Welchol (colesevelam HCl) for Oral Suspension should not be taken in its dry form.

Welchol for Oral Suspension is recommended for, but not limited to, use in appropriate pediatric patients as well as any patient who has difficulty swallowing.

**Phenylketonurics:** Welchol for Oral Suspension contains 27 mg phenylalanine per 3.75 gram dose.

In clinical trials, the adverse reactions observed in  $\geq 2\%$  of patients, and more commonly with Welchol than placebo (“sugar pill”), regardless of investigator assessment of causality seen in:

- Adult patients with high LDL (“bad” cholesterol) were: constipation, indigestion, nausea, accidental injury, weakness, sore throat, flu-like symptoms, runny nose, and muscle aches
- Pediatric patients with high “bad” cholesterol were: inflamed nasal passages and throat, headache, fatigue, creatine phosphokinase (a muscle enzyme) increase, runny nose, and vomiting
- Adult patients with type 2 diabetes, when added to other anti-diabetes medications, were: constipation, inflamed nasal passages and throat, indigestion, low blood sugar, nausea, and high blood pressure
- Adult patients with type 2 diabetes, when taken alone (monotherapy), were: back pain, headache, diarrhea, low blood sugar, C-reactive protein increased, constipation, upper respiratory tract infection, high blood sugar, high blood pressure, blood creatinine phosphokinase increased, gastroesophageal reflux disease (GERD), and tooth abscess

**You are encouraged to report negative side effects of prescription drugs to the FDA. Visit [www.fda.gov/medwatch](http://www.fda.gov/medwatch), or call 1-800-FDA-1088.**

For patients having difficulty affording their Daiichi Sankyo medication, please call the Daiichi Sankyo Patient Assistance Program at 1-866-268-7327 for more information or visit [www.dsi.com/news/patientassistance.html](http://www.dsi.com/news/patientassistance.html).

Please see full Prescribing Information for [Welchol](#).

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