

Type 2 Diabetes Fact Sheet

Diabetes Overview

- Diabetes is a chronic disease characterized by high blood glucose levels (hyperglycemia) that results from the inability of the body to properly use and/or produce insulin.¹ A hormone that is needed to convert sugar, starches and other food into energy, insulin is needed to survive.¹ There are three main types of diabetes:
 - **Type 1 Diabetes:** Previously known as juvenile diabetes or insulin-dependent diabetes, type 1 diabetes is usually diagnosed in children and young adults and requires daily injections of insulin.¹
 - **Type 2 Diabetes:** Previously called adult-onset diabetes or non-insulin dependent diabetes, type 2 diabetes occurs when the body does not properly use the insulin that is made (also called insulin resistance). In some people, the body may even lose its ability to make insulin over time.¹
 - **Gestational Diabetes:** A form of diabetes that occurs during pregnancy that may cause complications to an unborn baby.¹

Prevalence

- Approximately 25.8 million people in the United States (or 8.3 percent of the population) have diabetes.¹ Type 2 diabetes is the most common form of the disease, representing approximately 90 to 95 percent of all cases.¹ Diabetes is the seventh leading cause of death in the United States.¹
- Diabetes can affect people of all ages and backgrounds. It is estimated that 7.1 percent of non-Hispanic whites, 8.4 percent of Asian Americans, 11.8 percent of Hispanics, and 12.6 percent of non-Hispanic blacks over the age of 20 have diagnosed diabetes.¹
- The prevalence of diabetes is projected to more than double in the United States from 2005 to 2050.²
 - **Age:** Diabetes is projected to have the largest increase in older age groups.² In people ages 65 to 74 years old, diabetes is projected to increase by 200 percent.² In those 75 years of age and older, diabetes is likely to increase by 449 percent.²
 - **Race/Ethnicity:** Diabetes is expected to have the largest increase in prevalence in the Hispanic population.² For instance, it is estimated that diabetes will increase 127 percent among Hispanics, 107 percent among non-Hispanic blacks and 99 percent among non-Hispanic whites.²
- Adults with diabetes also are more likely to suffer from cardiovascular-related complications compared to those without diabetes.¹
 - **Heart Disease:** A two to four times higher death rate is seen from heart disease in people with diabetes.¹
 - **High Cholesterol:** About 58 percent of adults with diabetes also have high cholesterol.³
 - **Hypertension:** Approximately 67 percent of those with diabetes have high blood pressure.¹
 - **Stroke:** The risk for stroke is two to four times greater in adults with diabetes.¹



Risk Factors

- There are a number of factors that can increase the risk of developing type 2 diabetes including:

Conditions

- **Age:** Being over the age of 45.⁴
- **High Cholesterol:** Having high total cholesterol, which can consist of one or more of the following: high LDL or “bad” cholesterol, low HDL or “good” cholesterol, and/or high triglycerides.⁴
- **High Blood Pressure:** Having blood pressure 140/90 mm Hg or higher.⁴
- **Gestational Diabetes:** Women who have been diagnosed with gestational diabetes have a 35 to 60 percent chance of developing type 2 diabetes in the next 10 to 20 years.¹ Having one baby weighing more than 9 pounds also can increase risk.⁴
- **Pre-Diabetes:** A condition where people have blood glucose or A1C levels higher than normal but not high enough to be classified as type 2 diabetes.⁴

Behaviors

- **Overweight/Obese:** Being overweight or obese, based on Body Mass Index (BMI).⁴
- **Physical Inactivity:** Lack of physical exercise can lead to weight gain, which in turn can contribute towards the development of type 2 diabetes.⁴

Heredity

- **Genetics:** Having a family member (parent, brother or sister) with type 2 diabetes.⁴
- **Race/Ethnicity:** People of African American, Alaska Native, American Indian, Asian American, Hispanic/Latino or Pacific Islander American descent have increased risk.⁴

Prevent Long-Term Cardiovascular Complications

- High blood glucose levels over time can cause damage to nerves and blood vessels, leading to long-term cardiovascular complications such as heart disease and stroke.¹ Other diabetes-related complications can include blindness, eye problems, kidney disease, nervous system disease and amputation.¹
- In addition to keeping tight control over blood glucose levels in people with type 2 diabetes, aggressive treatment of high cholesterol also is recommended.¹ Recommended targets for blood glucose and cholesterol include:

A1C: Blood Glucose Levels

- **A1C Level:** A1C is a measurement of the average blood glucose control over a two to three month span of time.⁵ An A1C level of 7 percent is considered optimal in patients with diabetes.⁶
- **Before a Meal:** Blood glucose levels should be between 70 and 130 mg/dL.⁶
- **After A Meal:** Blood glucose are recommended to be less than 180 mg/dL one to two hours after a meal.⁶

Cholesterol

- **LDL or “Bad” Cholesterol:** Optimal levels are less than 100 mg/dL.⁵
- **HDL or “Good” Cholesterol:** Levels below 40 mg/dL are considered too low. Levels above 60 mg/dL are considered good.⁵
- **Triglycerides:** Less than 150 mg/dL are considered optimal.⁵

Treatment for Type 2 Diabetes

- While treatment plans for type 2 diabetes vary from individual to individual, some common components of treatment may include:
 - **Diet:** A well-balanced diet consisting of all the food groups.¹
 - **Exercise:** A proven method to help lower blood glucose levels as well as cholesterol levels.¹
 - **Glucose Monitoring:** Depending on the individual with type 2 diabetes, daily or weekly monitoring may suffice along with periodic A1C testing as directed by a healthcare professional.¹
 - **Glucose-Lowering Treatments:** These may include oral agents such as alpha-glucosidase inhibitors, biguanides, DPP-4 inhibitors, meglitinides, sulfonylureas, thiazolidinediones or a bile acid sequestrant.⁷ Some medicines may be used alone while others must be used in combination with other antidiabetes drugs depending on how they were approved by the FDA for use.⁷ Insulin also may be used to treat type 2 diabetes.¹
 - **Cholesterol-Lowering Treatments:** If lifestyle changes are not enough to get LDL or “bad” cholesterol to desired levels, a doctor may prescribe a cholesterol-lowering medication such as a bile acid sequestrant, fibric acid, a selective cholesterol absorption inhibitor, or a statin.⁸

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.

Important Safety Information About Welchol (colesevelam HCl) Continued

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, 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.

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

¹ Centers for Disease Control and Prevention. National Diabetes Fact Sheet: National Estimates and General Information on Diabetes and Prediabetes in the United States, 2011. Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, 2011.

² American Heart Association. Heart Disease and Stroke Statistics: 2013. *Circulation*. 2013. 127:e6-e245.

³ Centers for Disease Control and Prevention. Diabetes Program – Data & Trends, Risk Factor for Complications. Age-Adjusted Percentage of Adults Aged 18 Years or Older with Diagnosed Diabetes Who Have High Cholesterol, United States, 1995-2009.

⁴ National Diabetes Information Clearinghouse. Am I At Risk for Type 2 Diabetes? NIH Publication No. 12-4805. June 2012.

⁵ American Diabetes Association. Living with Diabetes - Healthy ABCs. Available at <http://www.diabetes.org/living-with-diabetes/complications/heart-disease/healthy-abcs/healthy-abcs.html>. Accessed on September 10, 2013.

⁶ American Diabetes Association. Living with Diabetes – Checking Your Blood Glucose. Available at <http://www.diabetes.org/living-with-diabetes/treatment-and-care/blood-glucose-control/checking-your-blood-glucose.html>. Accessed on September 10, 2013.

⁷ American Diabetes Association. Living with Diabetes – What Are My Options? Available at: <http://www.diabetes.org/living-with-diabetes/treatment-and-care/medication/oral-medications/what-are-my-options.html>. Accessed on September 10, 2013.

⁸ National Cholesterol Education Program. High Blood Cholesterol: What You Need to Know. Available at: <http://www.nhlbi.nih.gov/health/public/heart/cho/wnyntk.pdf>. Accessed on September 10, 2013.