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High LDL or "Bad" Cholesterol Fact Sheet

Cholesterol Overview

- Cholesterol is a waxy, fat-like substance needed for the body to function normally. While having some cholesterol in the body is necessary, having too much LDL or "bad" cholesterol can lead to complications such as heart disease and stroke.[1]

- Cholesterol is carried in the blood by particles called lipoproteins, which are made up of cholesterol on the inside and protein on the outside. There are several kinds of two lipoproteins, including:[1]

    - **Low-Density Lipoproteins (LDL):** Commonly referred to as "bad" cholesterol, this is the major type of lipoprotein that carries cholesterol in the bloodstream to the body and can lead to a build-up of cholesterol in the arterties.
    - **High-Density Lipoproteins (HDL):** Commonly referred to as "good" cholesterol, this type of liproprotein carries cholesterol back to the liver to remove it from the body.

- According to the National Cholesterol Education Project (NCEP), desirable or optimal cholesterol for adults are:[2]

    - **Total Cholesterol:** Less than 200 mg/dL is considered desirable. Anything above 240 mg/dL is considered "high" cholesterol.
    - **LDL or "Bad" Cholesterol**: Less than 100 mg/dL is considered optimal.
    - **HDL or "Good" Cholesterol**: Levels below 40 mg/dL are considered too low. Levels above 60 mg/dL are considered optimal.
    - **Triglycerides**: Less than 150 mg/dL are considered optimal.

- Most people do not realize that their "bad" cholesterol levels are too high, underscoring the importance of getting these levels checked (in addition to HDL or "good" cholesterol and triglycerides) every 5 years as recommended by the NCEP.[2] Screening consists of a blood test that measures the amounts of cholesterol in the blood.[2]

Prevalence

- High LDL or "bad" cholesterol can affect people of all ages and backgrounds.

- It is estimated that 71 million American adults have high LDL or "bad" cholesterol.[3] However, only 34 million have been treated for the condition and only 23 million have their levels under control.[3]

- While cholesterol screening is recommended every 5 years,[2] recent statistics demonstrate that only 68 percent of American adults report having this done.[1]

Risk Factors

- There are a number factors that can increase the risk of developing high LDL cholesterol including:

Conditions

- **Age/Gender:** Cholesterol levels tend to rise as people age.[1] Additionally, LDL cholesterol in women tends to rise more quickly than in men after age 55.[1]

- **Diabetes:** Having diabetes can increase the risk of developing high cholesterol.[1] People with diabetes either do not make insulin, or they do not use the insulin they do make as well as they should, which causes sugars to build up in the blood.[1]

Behaviors

- **Unhealthy Diet:** Some foods have certain types of fat -- saturated fat, trans fat and dietary cholesterol – that can raise cholesterol levels.[1]

- **Being Overweight:** Being overweight can increase LDL cholesterol and total cholesterol levels, while lowering HDL cholesterol levels.[1]

- **Physical Inactivity:** Lack of regular physical exercise can lead to weight gain, which in turn can raise LDL cholesterol levels.[1]

Heredity

- **Genetics:** High blood cholesterol can run in families. Genes influence how food is metabolized and how much cholesterol the body produces.[2] Genetics also can influence how much cholesterol the body makes and its ratio of "good" to "bad" cholesterol.[2] Additionally, an inherited genetic condition results in very high LDL cholesterol levels. This condition is called familial hypercholesterolemia.[1]

Treatment

- The main goal of treating high LDL or "bad" cholesterol is to lower the LDL to an optimal level, which is less than 100 mg/dL.[2] This will help reduce the development of cardiovascular complication such as a heart attack or stroke.[2]

- Generally, there are two approaches to treating high LDL or "bad" cholesterol: lifestyle modification and medications.[2]

- Eating a healthy diet, being physically active, maintaining a healthy weight and avoiding tobacco are some of the lifestyle changes that can help decrease high cholesterol.[1]

- If lifestyle changes are not enough to get LDL or "bad" cholesterol to desired levels, a physician may prescribe a cholesterol-lowering medication to aid in lowering levels.[1] Medications can include bile acid sequestrants, fibric acids, selective absorption inhibitors, or statins.[2] These medications can be used alone or in combination with one another, which is dependent on how they are approved for use.[2]

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.

Important Safety Information About Welchol (colesevelam HCl) Continued

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

In clinical trials, the adverse reactions observed in ≥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.

DSWC13102633
09/13

[1] Centers for Disease Control and Prevention. About High Blood Cholesterol. Available at: http://www.cdc.gov/cholesterol/. Accessed on September 10, 2013.
[2] National Cholesterol Education Program. High Blood Cholesterol: What You Need to Know. Available at: http://www.nhlbi.nih.gov/health/public/heart/chol/wyntk.pdf. Accessed on September 10, 2013.
[3] Morbidity and Mortality Weekly Report. Vital Signs: Prevalence, Treatment and Control of High Levels of Low-Density Lipoprotein Cholesterol – United States, 1999-2002 and 2005-2008. February 4, 2011. Vol. 60. No. 4.