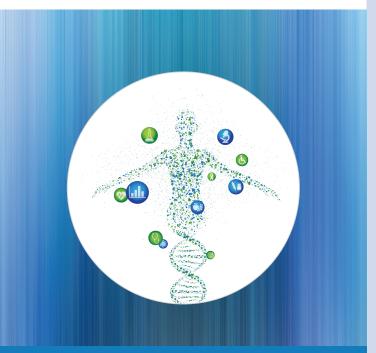
Cholesterol Medicines

FDA

This guide lists FDA-approved products currently available to treat high cholesterol levels and discusses the current approach to treating high cholesterol. This guide can help you talk with your healthcare provider about your medicine. The guide also has some general information about the safety of cholesterol-lowering medicines.

U.S. FOOD & DRUG



FDA Office of Women's Health www.fda.gov/womens Cholesterol is a kind of fat in your blood. Your body makes its own cholesterol, but you also get it from the foods you eat, such as meat; foods fried in animal fat, like lard, butter, or margarine; dairy products; or other foods.

Most people do not show any signs of high cholesterol. The only way to know your cholesterol levels for sure is to ask your healthcare provider for a cholesterol test. A cholesterol test can tell you about your:

- LDL (low-density lipoprotein) cholesterol: LDL is commonly called "bad" cholesterol. LDL can clog your arteries, and high LDL levels may make you more likely to have a heart event, such as a heart attack or stroke. A healthy LDL blood level is less than 100 mg/dL.
- HDL (high-density lipoprotein) cholesterol: HDL is sometimes called "good" cholesterol. People with high HDL blood levels may be less likely to have a heart event. A healthy HDL blood level is 60 mg/dL or higher.
- Total Cholesterol (TC): TC includes LDL, HDL, and other kinds of cholesterol. A healthy TC is less than 200 mg/dL.
- Triglycerides: Triglycerides are another type of fat measured as part of the cholesterol test. Triglyceride levels lower than 150 mg/dL are healthy. High triglycerides may increase your chance of having a heart attack or stroke. People with very high triglyceride levels (500 mg/dL or higher) are at risk for other health problems. Very high triglyceride levels are discussed in a separate section of this booklet.

High Cholesterol Levels

Some people have too much cholesterol in their blood. Cholesterol can build up on the inside of the blood vessels in your heart as well as other blood vessels in your body. If too much cholesterol builds up in the blood vessels in your heart, the blood cannot flow through to your heart and may lead to a heart attack. People with high cholesterol, especially high LDL, are more likely to have a heart event, such as a heart attack or stroke, or need surgery or a procedure to open up the blood vessels of the heart (bypass surgery, angioplasty, or stent placement).

A heart-healthy lifestyle may help lower your cholesterol and your chance of having a heart event at all ages. A heart-healthy lifestyle includes reducing the amount of total and saturated fat in your diet, participating in regular aerobic exercise, and losing weight (if you are overweight or obese).

Lowering LDL with certain medicines may decrease your chance of having a heart event. But not everyone with high cholesterol needs medicine. Whether or not you should start a cholesterol-lowering medicine depends on a few things: if you already have heart (cardiovascular) disease, your age, your cholesterol levels, and other factors. Your healthcare provider can help you decide about taking a cholesterol-lowering medicine, such as a statin.

In most cases, if you need to take a cholesterol-lowering medicine, your healthcare provider may consider prescribing a statin first. You can discuss this more with your healthcare provider.

Very High Triglyceride Levels (Severe Hypertriglyceridemia)

People with very high triglyceride levels (500 mg/dL or higher) may be more likely to develop acute pancreatitis. Acute pancreatitis is swelling and irritation of the pancreas that feels like sudden, severe stomach pain. In some cases, the pain may get better, but in other cases you could have a fever, severe dehydration, and get very sick and need to go to the hospital for care to save your life. The most common causes of acute pancreatitis are gallstones, excess alcohol use, and taking certain medicines. Very high triglycerides may cause acute pancreatitis even in people who do not have gallstones or drink alcohol.

Many things can cause very high triglyceride levels, such as genetic causes (passed down from a parent), uncontrolled diabetes, taking certain medicines, being obese or overweight, alcohol use, pregnancy, and thyroid disease. People with high triglycerides should follow a low-fat diet with a goal of weight loss (if overweight or obese) and should not drink alcohol or take certain medicines. People with diabetes are typically instructed to follow a meal plan and take their diabetes medicine as prescribed to improve control of their blood sugar levels.

Some people may need to take medicine in addition to lifestyle changes (diet and exercise) to lower their triglyceride levels. If you have high triglyceride levels, you should talk to your healthcare provider.

Medicines to Control Cholesterol and Triglycerides

There are different kinds of medicines to lower high cholesterol, triglycerides, or both.

- HMG-CoA Reductase Inhibitors (also called statins)
- Cholesterol Absorption Inhibitors
- Proprotein Convertase Subtilisin Kexin Type 9 (also called PCSK9 inhibitors)
- Adenosine Triphosphate-Citrate Lyase (ACL) Inhibitors
- Cholesterol-Lowering Combination Medicines
- High Blood Pressure and Cholesterol-Lowering Combination Medicines
- Omega-3-Acid Ethyl Esters
- Bile Acid Sequestrants
- Fibric Acid Derivatives (also called fibrates)
- Niacin

Use this guide to help you talk with your healthcare provider about your cholesterol or triglyceride medicine. Ask your healthcare provider about the benefits and risks of taking your medicine. This guide only talks about some of the risks.

Tell your healthcare provider about any problems you are having. Your healthcare provider will help you find the medicine that is best for you.

Also, tell your healthcare provider if you are pregnant, breastfeeding, or planning to become pregnant. Ask your healthcare provider to tell you about the benefits and risks of taking medicine when you are pregnant.

The different kinds of cholesterol and triglyceride medicines are listed on the next few pages. The medicines are listed in groups. The brand names and generic names are given for the medicines in each group.

HMG-CoA Reductase Inhibitors (also called Statins)

Generic Name	Brand Name
atorvastatin	Lipitor
fluvastatin	Lescol XL
lovastatin	Altoprev
pravastatin	Pravachol
pitavastatin	Livalo and Zypitamag
rosuvastatin	Crestor and Ezallor Sprinkles
simvastatin	Flolipid and Zocor

Statins: What You Should Know

These medicines treat high cholesterol and high triglycerides. Certain statins have been shown to reduce the risk of some heart problems or procedures in people who have heart disease or are at high risk of heart disease because of other conditions, such as diabetes or high blood pressure. These problems can include heart attack, stroke, or other heart problems requiring hospitalization (including congestive heart failure). Certain statins may reduce the risk of or need for heart procedures, such as bypass surgery, angioplasty, or stent placement. Certain statins have also been shown to reduce the risk of dying from a heart attack, stroke, or other heart event.

Before taking these medicines, tell your healthcare provider if you:

- Have any allergies, including allergies to medicines
- Are pregnant or planning to become pregnant
- Are breastfeeding or planning to breastfeed
- Have liver problems
- Have kidney problems
- Have diabetes
- Have unexplained muscle aches or weakness
- Drink more than two glasses of alcohol daily
- Have thyroid problems

Tell your healthcare provider and pharmacist about all the medicines you take, including prescription and non-prescription medicines, vitamins, herbal supplements, or other nutritional supplements. Especially tell your healthcare provider if you are taking medicines for your cholesterol, any infections, your immune system, heart failure, seizures, diabetes, heartburn or stomach ulcers, or birth control pills.

Warnings

Statins can cause serious side effects, including:

- Muscle problems that can sometimes lead to serious kidney problems, including kidney failure.
- Liver problems. Your healthcare provider should do blood tests to check your liver before starting these medicines.

Statins: What You Should Know

Common Side Effects

- Headache
- Nausea
- Diarrhea
- Constipation
- Muscle pain
- Back pain
- Upset stomach

- Abdominal pain
- Weakness
- Joint pain
- Flatulence
- Stomach pain
- Rash

Warning Signs

If you are taking a statin, get medical help right away if you have any of these signs or symptoms:

- Allergic reaction, including hives, rash, or swelling in other parts of your body
- Brown or dark-colored urine
- Changes in urination
- Muscle problems, like weakness, tenderness, or pain that happens without a known reason (like exercise or injury)
- Skin or eyes look yellow
- Skin rash, itching, or redness (moderate to severe)
- Weakness in part of your body

Cholesterol Absorption Inhibitors

Generic Name	Brand Name
ezetimibe	Zetia

Cholesterol Absorption Inhibitors: What You Should Know

This medicine treats high cholesterol.

Before taking this medicine, tell your healthcare provider if you:

- Have any allergies, including allergies to medicines
- Are pregnant or planning to become pregnant
- Are breastfeeding or planning to breastfeed
- Have liver problems
- Experience unexplained muscle pain, tenderness, or weakness

Tell your healthcare provider and pharmacist about any prescription and non-prescription medicines you are taking or plan to take, including natural or herbal remedies.

Warnings

This medicine can cause serious side effects when taken with other cholesterol-lowering medicines, including:

- Abnormal blood tests for liver function
- Serious muscle problems

Common Side Effects

- Diarrhea
- Joint pain
- Feeling tired

Warning Signs

If you are taking ezetimibe, get medical help right away if you have any of these signs or symptoms:

- Allergic reaction, including hives, rash, or swelling in other parts of your body
- Muscle problems, like weakness, tenderness, or pain that happens without a good reason (like exercise or injury)
- Brown or dark-colored urine
- Skin or eyes look yellow

Proprotein Convertase Subtilisin Kexin Type 9 (also called PCSK9 Inhibitors)

Generic Name	Brand Name
alirocumab	Praluent
evolocumab	Repatha

PCSK9 Inhibitors: What You Should Know

These medicines treat high cholesterol and decrease the chances of having a heart attack, stroke, or certain types of heart problems requiring hospitalization in people with known heart (cardiovascular) disease.

Before taking these medicines, tell your healthcare provider if you:

- Have any allergies, including allergies to medicines
- Are pregnant or planning to become pregnant
- Are breastfeeding or planning to breastfeed

Tell your healthcare provider and pharmacist about all the medicines you take, including prescription and non-prescription (over-the-counter) medicines, vitamins, and herbal supplements.

Warnings

These medicines can cause serious side effects, including:

• Serious allergic reactions

Common Side Effects

- Back pain
- Common cold symptoms, or flu or flu-like symptoms
- Redness, itching, swelling, pain, or bruising at the injection site
- Runny nose
- Sore throat

Warning Signs

If you are taking a PCSK9 inhibitor, get medical help right away if you have any of these signs or symptoms:

- Allergic reaction, including hives, rash, or swelling in other parts of your body
- Trouble breathing or swallowing

Adenosine Triphosphate-Citrate Lyase (ACL) Inhibitors

Generic Name	Brand Name
bempedoic acid	Nexletol

ACL Inhibitors: What You Should Know

This medicine treats high cholesterol.

Before taking this medicine, tell your healthcare provider if you:

- Have any allergies, including allergies to medicines
- Have gout
- Have tendon problems
- Are pregnant or planning to become pregnant
- Are breastfeeding or planning to breastfeed
- Have kidney problems
- Have liver problems

This medicine may affect the way other medicines work, and other medicines may affect how this medicine works. Tell your healthcare provider and pharmacist about all the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements. Especially tell your healthcare provider and pharmacist if you take or plan to take other cholesterol-lowering medicines, fluoroquinolones, or cortisone medicines.

Warnings

This medicine may cause serious side effects, including:

- Increased levels of uric acid in your blood. High levels of blood uric acid may lead to gout.
- Tendon rupture or injury.

Common Side Effects

- Common cold symptoms, flu, or flu-like symptoms
- Bronchitis
- Back pain
- Stomach pain
- Abnormal laboratory test for liver function
- Muscle spasms
- Shoulder, arm, or leg pain (mild)
- Anemia
- Increased liver enzymes

ACL Inhibitors: What You Should Know

Warning Signs

If you are taking an ACL inhibitor, get medical help if you have any of these signs or symptoms:

- Bruising, pain or swelling in an arm, shoulder, or ankle
- Fast or irregular heartbeat
- Joints red, tender, or swollen, severe foot pain
- Sudden joint snapping or "popping" sound
- Unable to move or put weight on joint or limb

Cholesterol-Lowering Combination Medicines

Generic Name	Brand Name
ezetimibe and bempedoic acid	Nexlizet
ezetimibe and rosuvastatin	Roszet
ezetimibe and simvastatin	Vytorin

Cholesterol-Lowering Combination Medicines: What You Should Know

These medicines are made up of two different kinds of cholesterol medicines. Some of these medicines appear alone on other lists in this guide. Look for the generic or brand names on the other lists.

Before taking these medicines, tell your healthcare provider if you:

- Have any allergies, including allergies to medicines
- Are pregnant or planning to become pregnant
- Are breastfeeding or planning to breastfeed
- Experience unexplained muscle pain, tenderness, or weakness
- Have tendon problems
- Have gout
- Have liver problems
- Have kidney problems
- Have thyroid problems
- Have diabetes
- Drink more than two servings of alcohol daily

These medicines may affect the way other medicines work, and other medicines may affect how these medicines work. Tell your healthcare provider and pharmacist about all the medicines you take, including prescription and non-prescription medicines, vitamins, herbal supplements, or other nutritional supplements. Especially tell your healthcare provider and pharmacist if you are taking medicines for your cholesterol, fluoroquinolones, medicines for any infections, your immune system, heart failure, seizures, diabetes, heartburn or stomach ulcers, birth control pills, or cortisone medicines.

Warnings and Side Effects

The warnings and side effects for these medicines are the same as those listed for each of the generic medicines.

High Blood Pressure and Cholesterol-Lowering Combination Medicines

Generic Name	Brand Name
amlodipine and atorvastatin	Caduet

High Blood Pressure and Cholesterol-Lowering Combination Medicines: What You Should Know

This medicine is made up of two different kinds of medicines. This medicine is used to treat both high blood pressure and high cholesterol.

Atorvastatin is a cholesterol-lowering medicine. Look for the **other names** of **atorvastatin** on the list of **HMG-CoA Reductase Inhibitors ("statins")** on page **three** of this guide. The **warnings** and **side effects** for **atorvastatin** are the same as those listed earlier for "statins."

Amlodipine is a blood pressure medicine. Some of the **warnings** and **side effects** for **amlodipine** are listed below.

Before taking this medicine, tell your healthcare provider if you:

- Have any allergies, including allergies to medicines
- Are pregnant or planning to become pregnant
- Are breastfeeding or planning to breastfeed
- Have liver or kidney problems
- Have a heart condition
- Have unexplained muscle aches or weakness
- Have diabetes
- Have thyroid problems
- Drink more than two glasses of alcohol daily

Tell your healthcare provider and pharmacist about all the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements. Especially tell your healthcare provider and pharmacist if you take medicines for:

- Your immune system
- Infections
- Cholesterol
- Hepatitis C virus
- Birth control
- Heart failure
- HIV (AIDS)
- Other viruses

High Blood Pressure and Cholesterol-Lowering Combination Medicines: What You Should Know

Warnings

This medicine can cause serious side effects, including:

- Serious muscle problems that can lead to kidney problems, including kidney failure.
- Serious liver problems. Your healthcare provider should do blood tests to check your liver before starting this medicine.
- Low blood pressure or dizziness.
- Muscle rigidity, tremor, and abnormal muscle movement.

Common Side Effects

- Diarrhea
- Swelling of your legs or ankles
- Nausea
- Upset stomach
- Muscle and joint pain
- Changes in some laboratory blood tests

Warning Signs

If you are taking a high blood pressure and cholesterol-lowering combination medicine, get medical help right away if you have any of these signs or symptoms:

- Chest pain
- Serious rashes
- Swelling of the face, eyes, lips, tongue, arms, or legs
- Fainting
- Muscle problems like weakness, tenderness, or pain that happens without a good reason (like exercise or injury)
- Skin or eyes look yellow

Omega-3-Acid Ethyl Esters (also called Omega-3 fatty acids)

Generic Name	Brand Name
omega-3-acid ethyl esters	Lovaza
icosapent ethyl	Vascepa

Omega-3-Acid Ethyl Esters: What You Should Know

These medicines lower very high triglycerides in adults.

Icosapent ethyl is used along with other medicines (statins) to reduce the risk of heart attack, stroke, and certain types of heart issues requiring hospitalization in adults with heart (cardiovascular) disease or diabetes and two or more additional risk factors for heart disease.

Before taking these medicines, tell your healthcare provider if you:

- Have any allergies, including allergies to medicines
- Are pregnant or planning to become pregnant
- Are breastfeeding or planning to breastfeed
- Have diabetes
- Have thyroid problems
- Have a liver problem
- Have a pancreas problem
- Are allergic to fish or shellfish
- Have gout
- Have an irregular heartbeat

Tell your healthcare provider and pharmacist about all the medicines you take, including prescription and non-prescription (over-the-counter) medicines, vitamins, and dietary or herbal supplements. These medicines can interact with certain other medicines that you are taking. Especially tell your healthcare provider if you take medicines that affect your blood clotting (anticoagulants or blood thinners).

Warnings

These medicines can cause serious side effects, including:

- Heart rhythm problems
- Possible allergic reactions if you are allergic to fish or shellfish
- Bleeding
- Changes in certain blood tests used to check your liver function and cholesterol levels

Omega-3-Acid Ethyl Esters: What You Should Know

Common Side Effects

- Burping
- Joint or muscle pain
- Swelling of the hands, legs, or feet
- Constipation
- Gout
- Heart rhythm problems
- Upset stomach
- Change in sense of taste

Warning Signs

If you are taking an omega-3 fatty acid, get medical help right away if you have any of these signs or symptoms:

- Allergic reaction, including hives, rash, or swelling in other parts of your body
- Fast or irregular heartbeat
- Increased or unusual bleeding
- Joints red, tender, or swollen

Bile Acid Sequestrants

Generic Name	Brand Name
cholestyramine	Prevalite
colesevelam	Welchol
colestipol	Colestid

Bile Acid Sequestrants: What You Should Know

These medicines treat high cholesterol.

Before taking these medicines, tell your healthcare provider if you:

- Have any allergies, including allergies to medicines.
- Are pregnant or planning to become pregnant. These medicines may interfere with how you absorb vitamins.
- Are breastfeeding or planning to breastfeed. These medicines may interfere with how you absorb vitamins.
- Have pancreas problems. Very high levels of triglycerides (more than 2,000 mg/dL) may increase the risk of pancreatitis.
- Have bleeding problems, chronic constipation, gallbladder problems, heart disease, hemorrhoids, phenylketonuria, previous intestinal surgery or bowel blockage, stomach ulcers, or thyroid disease.
- Bile acid sequestrants can bind to and slow down or reduce the absorption into the bloodstream of many medicines. Talk with your healthcare provider about how to schedule taking your other medicines around taking a bile acid sequestrant.
- To reduce the risk of constipation, drink plenty of fluids and increase the amount of fiber in your diet while using this medicine.
- Avoid slowly sipping or holding cholestyramine-containing liquid in your mouth for prolonged periods of time because it can damage tooth surfaces. Practice good oral hygiene while taking this medicine.
- Tell your healthcare provider and pharmacist about all the medicines you take, including prescription and non-prescription medicines, vitamins, herbal supplements, or other nutritional supplements. Especially tell your healthcare provider if you are taking any of the following:
 - Birth control pills
 - Blood thinners
 - Cyclosporine
 - Diabetes medicines
 - Heart or blood pressure medicines
 - Mycophenolic acid
 - Phenobarbital
 - Phenytoin
 - Thyroid hormones

Bile Acid Sequestrants: What You Should Know

Common Side Effects

- Increased burping
- Heartburn
- Constipation (mild)
- Gas
- Indigestion
- Nausea
- Diarrhea

Warning Signs

If you are taking a bile acid sequestrant, get medical help if you have any of these signs or symptoms:

- Constipation (moderate to severe)
- Prolonged period of time without having a bowel movement
- Abdominal or stomach pain
- Vomiting
- Sudden weight change
- Increased or unusual bleeding

Fibric Acid Derivatives (also called Fibrates)

Generic Name	Brand Name
fenofibrate	Antara, Fenoglide, Lipofen, Tricor, and Triglide
fenofibric acid	Fibricor and Trilipix
gemfibrozil	Lopid

Fibric Acid Derivatives (Fibrates): What You Should Know

These medicines treat high cholesterol and high triglycerides.

Before taking these medicines, tell your healthcare provider if you:

- Have any allergies, including allergies to medicines
- Are pregnant or planning to become pregnant
- Are breastfeeding or planning to breastfeed
- Have liver problems
- Have kidney problems
- Have heart problems
- Have muscle pain or tenderness
- Have gallbladder problems
- Have pancreas problems
- Have had a blood clot, like a DVT or PE

Tell your healthcare provider and pharmacist about all the medicines you take, including prescription and non-prescription medicines, vitamins, herbal supplements, or other nutritional supplements. Especially tell your healthcare provider and pharmacist if you are taking any medicines that affect your blood clotting (anticoagulants or blood thinners), medicines that suppress your immune system, other cholesterol-lowering medicines, or colchicine.

Warnings

These medicines may cause serious side effects, including:

- Serious muscle injury that can lead to kidney injury
- Abnormal laboratory tests of liver function
- Abnormal tests of kidney function
- Abnormal tests of blood cells
- Changes in other blood tests for cholesterol levels
- Gallstones
- Bleeding, when taken with certain blood-thinning medicines
- Pancreatitis
- Severe allergies
- Blood clots

Fibric Acid Derivatives (Fibrates): What You Should Know

Common Side Effects

- Abnormal blood tests of liver function
- Runny nose
- Stomach pain
- Back pain
- Headache
- Nausea
- Constipation

Warning Signs

If you are taking a fibrate, get medical help right away if you have any of these signs or symptoms:

- Allergic reaction, including hives, rash, itching, redness, or swelling
- Shortness of breath, chest pain, or coughing up blood
- Warmth, pain, tenderness, swelling, or skin redness in leg or thigh
- Muscle problems like weakness, tenderness, or pain that happens without a reason (like exercise or injury)
- Brown or dark-colored urine
- Skin or eyes look yellow
- Severe and sudden pain in upper abdomen
- Nausea or vomiting (severe)
- Clay-colored stools

Niacin

Generic Name	Brand Name
niacin (nicotinic acid, vitamin B3)	Niacor and Niaspan

Niacin: What You Should Know

This medicine treats high cholesterol and high triglycerides.

Before taking this medicine, tell your healthcare provider if you:

- Have any allergies, including allergies to medicines
- Are pregnant or planning to become pregnant
- Are breastfeeding or planning to breastfeed
- Have liver problems
- Have stomach ulcers

- Have bleeding problems
- Have diabetes
- Have gout
- Have kidney problems

Tell your healthcare provider and pharmacist about all the medicines you take, including prescription and non-prescription medicines, vitamins, herbal supplements, or other nutritional supplements containing niacin or nicotinamide. Especially tell your healthcare provider and pharmacist if you take other medicines to lower cholesterol or triglycerides, aspirin, blood pressure medicines, medicines that affect your blood clotting (anticoagulants or blood thinners), or drink alcohol daily.

Warnings

This medicine can cause serious side effects, including:

- Severe liver problems
- Unexplained muscle pain, tenderness, or weakness
- High blood sugar levels

Common Side Effects

- Flushing (redness of the face or neck)
- Diarrhea
- Nausea

- Vomiting
- Cough
- Skin rash or itching

Warning Signs

If you are taking niacin, get medical help if you have any of these signs or symptoms:

- Fast or irregular heartbeat
- Fainting
- Dizziness

- Muscle problems like weakness, tenderness, or pain
- Brown or dark-colored urine
- Skin or eyes look yellow

Questions to Ask Your Healthcare Provider

What is the name of the medicine I am taking?

What are the potential side effects?

What other prescription medicines should I avoid while taking my cholesterol medicine?

What foods (such as grapefruit juice), herbs (like St. John's wort, ginkgo, goldenseal), or non-prescription (over-the-counter) medicines should I avoid?

When should I take each medicine? How many times per day do I take each medicine?

Can I take my medicine if I am pregnant or breastfeeding?

Sign Up for a Pregnancy Registry

Pregnancy Exposure Registries are research studies that collect information from women who take prescription medicines or vaccines during pregnancy.

Pregnancy registries can help women and their doctors learn more about how cholesterol medicines affect women during pregnancy.

The FDA does not conduct pregnancy studies, but it keeps a list of registries.

Check to see if there is a registry for your cholesterol medicine or other medicines at www.fda.gov/pregnancyregistries.



This document was developed by

FDA Office of Women's Health

www.fda.gov/womens

To Learn More:

National Heart, Lung, and Blood Institute Health Information Center Phone: 1-877-NHLBI4U https://www.nhlbi.nih.gov/health-topics/high-blood-cholesterol

> MedlinePlus https://medlineplus.gov/cholesterol.html

This guide should not be used in place of talking to your healthcare provider or reading the label on your medicine bottle. The medicine and risk information in this guide may change and is not all inclusive. Cholesterol medicines and information in this guide are current as of June 2022.

