Step One Foods Definitive Guide to Cholesterol and Statins

BY ELIZABETH KLODAS MD, FACC

About the Author

Dr. Klodas is a cardiologist and founder of Step One Foods. She trained at Mayo Clinic and Johns Hopkins, and practices in Minneapolis, Minnesota. She is also author of the American College of Cardiology's, "Slay the Giant: The Power of Prevention in Defeating Heart Disease".

Dr. Klodas had dedicated her career to helping people prevent and reverse heart disease without relying solely on medications. According to Dr. Klodas "there is a lot of information about cholesterol and heart disease out there, and much of it is wrong". She wrote this guide to empower patients with scientifically based facts about their treatment options.

Step One Foods was founded based upon Dr. Klodas' work that demonstrated most cholesterol abnormalities can be markedly improved through dietary change. Step One's foods were formulated scientifically to deliver the precise levels of nutrients needed to improve heart health and lower cholesterol. And it works. On average, customers have reported a 39 point LDL (bad) cholesterol reduction in just 30 days.

If you would like to see if Step One Foods will work for you, **try a sample.** Or take the **30-day challenge** and use promo code **CHALLENGE** to save 15% and help you get started. You'll be happy you did.

And if you'd like to learn how to use Step One Foods to reduce your need for statins, make sure you read page 7.

This document was created to help you gain a better understanding of cholesterol, statins, statin side effects and statin alternatives. We do not advocate that you stop or reduce any medication before talking with your physician.

Why cholesterol matters

Cholesterol is a waxy, fat-like substance found in the walls of every cell within our bodies. We also use cholesterol to make hormones, bile acids, vitamin D, and other substances. So cholesterol is important to our bodies' structure and function.

However, if there is too much cholesterol circulating in the bloodstream, some of the excess can become trapped in artery walls. This build up is called plaque. If enough of it accumulates, plaque can narrow vessels and make them less flexible, causing "hardening of the arteries".

Plaque accumulation can happen in blood vessels anywhere in the body, including the coronary arteries of the heart. If the coronary arteries become partly blocked by plaque, blood flow to heart muscle can become reduced enough that

people experience chest pain or unusual shortness of breath with activity. This is called angina.

Some cholesterol-rich plaques can also become unstable. Because they have a thin covering, they can burst, triggering the formation of a blood clot at the site of plaque rupture. If the blood clot is big enough, it can end up blocking blood flow through the artery—causing a heart attack.

Lowering cholesterol (especially LDL (bad) cholesterol) has been shown to reduce the risk of developing blockages and to stabilize plaque that is already there. There is even data showing REVERSAL of blockages with lifestyle change and lowering LDL to very low levels. No wonder there's so much effort expended on making sure everyone's LDL is under control.

In general, most cardiologists would say that an LDL below 130 mg/dL is acceptable for otherwise healthy individuals. As you accumulate risk factors for heart disease (high blood pressure, family history of heart disease, smoking, low HDL (good) cholesterol), aiming for an LDL below 100 mg/dL is preferable. If you already have heart disease or have diabetes, getting your LDL below 70 mg/dL is ideal.

What are statins?

Statins are a group of medications used to lower cholesterol. They are the most frequently prescribed drugs on the planet. The category includes Crestor® (rosuvastatin), Lipitor® (atorvastatin), Zocor® (simvastatin), Pravachol® (pravastatin), Mevacor® (lovastatin) Lescol® (fluvastatin), and Livalo® (pitavastatin). It is estimated that 70 Million Americans are candidates for statin therapy, primarily on the basis of high cholesterol levels.

And there is no question that some people SHOULD take these medications, because the data is so consistent that their outcomes (not just cholesterol numbers) are improved. The 4 groups that appear to clearly benefit include:

- Those with known coronary artery or vascular disease (people who have a stent, have had a heart attack, stroke or bypass surgery, and those with otherwise documented atherosclerosis).
- Those with genetically driven very high LDL (bad) cholesterol numbers (LDL > 190 mg/dL)
- Those with diabetes
- Those with a 7.5% or greater risk of experiencing a heart or vascular event over the next 10 years, as determined by a risk calculator

It should be noted that individuals with documented heart or vascular disease should be on statins REGARDLESS OF THEIR CHOLESTEROL NUMBERS.

But for the other 3 groups, modifying lifestyle can have a large impact on whether or not they need to remain on statin drugs. For example, lifestyle modification can reverse diabetes, markedly impact your calculated risk, and even bring very high LDL levels below 190 mg/dL.

How statins work

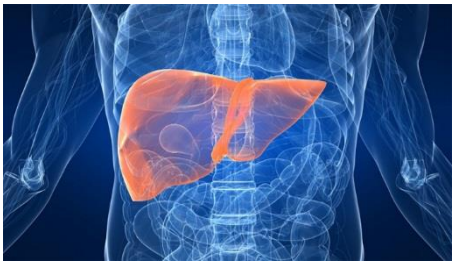
Cholesterol is packaged and processed in the liver and statins inhibit a liver enzyme called HMG-CoA reductase. When HMG-CoA reductase is inhibited, cholesterol production in the liver slows down. When cholesterol production in the liver falls, circulating levels of LDL (bad) cholesterol drop.
In general, at maximum dose, statins can lower LDL by 30-50%.

Statin side effects

People who develop side effects from statins are referred to as "statin intolerant". It is estimated that approximately 20% of people run into difficulties while taking these medications.

If you look around the internet, you will be overwhelmed by stories of horrible things happening because someone went on a statin. Remember – no one takes time to write how well they're doing on a drug. The information is therefore fundamentally slanted.

However, statin side effects are real and you need to be aware of what they are. Here's the rundown:



Liver

Statins work in the liver, where they're only supposed to affect the HMG-CoA reductase system. But in some people statins have a broader liver effect and that gets translated into elevated liver enzyme tests. This is not something you would feel – rather it is something that would show up in a blood test.

If they are to be affected, liver function tests (LFTs) tend to become abnormal early after

starting a statin or after increasing the dose. Sometimes, they go up slightly as you start and then settle down over time. This is not the sort of situation where you are on a statin for years and then all of a sudden your liver starts to malfunction.

The liver effect is almost always reversible, but is **more likely with higher statin doses**. The LFTs go right back down to baseline if you stop the statin medication.

It's important to point out that marked LFT abnormalities related to statin use are uncommon. And if you do see a liver effect with one statin, it does not mean you will see it with a different statin preparation. Each one of the statins is unique in its chemical structure (which is why each of them had a patent at one point in time).

For monitoring purposes, you should have a baseline LFT assessment before you go on statin medications and then periodically once you're on them (especially after starting on the medication or going up on the dose). Long term, LFT monitoring (for statin treatment alone) is not required if your LFT numbers have been stable.

Muscle

Muscle side effects are the most common reason people stop taking these medications. Although very few patients experienced muscle side effects during the clinical trials that led to the medications getting approved, in real world practice, about 10 to 20% of patients taking the medications report achiness.

The achiness tends to affect large muscle groups and tends to be symmetrical. Patients tend to complain of back pain or bilateral leg pain or shoulder/upper arm pain. A sore left index finger, for example, is unlikely to be caused by statins. The achiness may be felt more in the joints than in the muscles, but still tends to affect larger joints – and on both sides of the body.

The achiness can vary in severity from person to person. For some people it's very subtle – it just takes them longer to recover from strenuous exercise. For others it's much more extreme and actually interferes with their ability to move without pain.

The reason why some people develop muscle side effects and others don't is not clear. Having a slight build, having a history of muscle achiness, having low thyroid function, and/or having a low vitamin D level all increase the likelihood that muscle side effects will occur. But even people without any of those risk factors can develop achiness.

Certain medication combinations can make achiness (and other statin side effects) more likely. Be sure to always ask your doctor or pharmacist if a new medication being prescribed has the potential to interact with your statin. Consuming grapefruit/grapefruit juice in large amounts can also increase the risk of statin toxicity.

One thing is clear – **the higher the statin dose, the more likely the muscle achiness.** So minimizing the dose you need helps reduce your chances of developing muscle side effects.

Finally, not all muscle achiness is due to statins. Sometimes it's difficult to know if you're sore because you just engaged in a new physical activity, because you have arthritis, or because you're on a cholesterol lowering medication. In some situations, this can be really challenging to sort out.

The good news is that achiness caused by statins tends to go away very quickly once the medication is stopped. People usually report marked improvement within days, and being back to baseline normal within 2-4 weeks of stopping the drug.

Unlike liver side effects, muscle side effects do not necessarily appear right away. Instead, they tend to appear sometime during the first 6 months of starting the medication (or increasing the dose). But some people are on statins for well over a year before they notice this side effect. Nevertheless, if you do not get achy within the first 6 months of treatment, chances are high you will not experience this side effect going forward.

Just because you see this effect with one statin does not mean you will see it with a different statin preparation. If you've experienced muscle achiness with 3 different statins, chances are high that you will experience achiness with the remaining preparations.

Brain

Neurologic side effects are rare, but can occur. People tend to report fogginess, being "less sharp" or more forgetful. This again tends to reverse with stopping or changing the medication.

It's important to point out that, on balance, published studies have shown that statins appear to be somewhat protective against dementia. This is probably because people on statins have lower rates of stroke.

Diabetes

The association between statin therapy and a higher risk of developing diabetes is something that has only recently been appreciated. The reason for this association is not understood, but it does not appear to be entirely explained by background lifestyle factors. In other words, there is something unique to statins alone that is driving higher rates of diabetes in statin users. **The risk of diabetes is higher with higher doses of statins used.**

The risk is not overwhelming, and the general consensus is that the cardiovascular benefits of statins far outweigh diabetes risk. However, if you are on these medications it behooves you to be sure you are attending to any other risk factors for developing diabetes - and that you are following a very strategic eating plan.

Other considerations

If you search the internet, you will find lots of other potential associations between statins and unwanted health effects including digestive problems, hair loss, cataracts, tendon rupture, kidney damage, myositis (dangerous inflammation of the muscles, different from the simple achiness described above), and even Cancer

All of these side effects are possible – because we are all completely individual. But it is important to point out that they appear to be very rare. That's not to say a ruptured tendon or cancer is minor. But the chance than anyone taking a statin will experience one of these side effects is truly small.

Nevertheless, your body on a statin is different than your body off of a statin.

For many people being on a statin makes sense because the benefits far outweigh the risks. If you have known coronary artery disease, you are diabetic, or you have a very high LDL level (>190 mg/dL), taking a statin make sense.

For those without heart disease, diabetes, or genetically driven very high LDL levels, lowering cholesterol and reducing the risk of heart disease can often be accomplished without adding medications to the mix.

Statin alternatives

As many as 20% of people who have been prescribed statins cannot take them because they develop one or more side effects. 30-40% of people prescribed statins never fill the prescription in the first place. Clearly there are a lot of people who are looking for something different to improve their cholesterol numbers. Here are some options:

Step One Foods

After all, this is why these products were created. We have combined real food ingredients, all of which have been shown to lower cholesterol, into a convenient and minimally disruptive eating system. Just eat our foods twice per day in exchange for something you were eating before. And ideally build on that by incorporating more whole, plant-based foods the rest of the day.

Step One Foods are unique because they supply scientifically validated levels of four critical nutrients needed to improve cholesterol profiles and cardiovascular health:

- Fiber – Fiber in whole foods binds to cholesterol particles in the digestive system and moves them out of the body
- Antioxidants – Antioxidants help prevent the build-up of plaque in blood vessels.

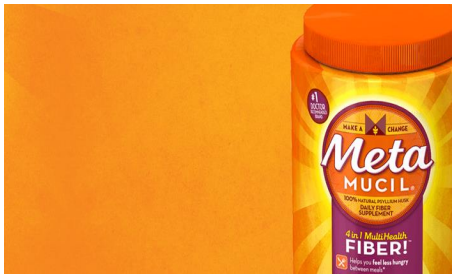
- Plant Sterols – Plant Sterols block cholesterol absorption in the digestive tract.
- Omega-3 fatty acids – Omega-3s reduce inflammation and help raise HDL and lower triglycerides

The big bonus of using Step One is that when you eat these foods, you are not just helping to lower your cholesterol levels. You are also helping lower blood pressure, improve blood sugar levels and lower calorie intake. So you are impacting several risk factors for heart disease all at once.

The data on the power of food to lower cholesterol, improve cardiovascular health and lower rates of heart attack and stroke is vast and consistent. In fact, **improving lifestyle, and especially food intake, is more impactful in affecting outcomes than any drug or procedure.**

You can check how Step One Foods are working by checking your cholesterol profile. To see whether you are a "food responder", get a baseline cholesterol profile prior to starting the food program. Eat Step One Foods twice per day for at least 30 days and go back for a repeat fasting cholesterol profile. It is important to **make sure you are eating the foods twice per day right up until the night before the blood test**.

Not everyone who changes their diet will see a dramatic change in their cholesterol – just like not everyone who reduces salt in their diet will see a dramatic drop in blood pressure. But profound changes are possible. To date, in Step One customers with high LDL not taking statin medications, the average self-reported LDL drop after using Step One Foods has been 39 points. Some individuals have reported LDL reductions as high as 70-80 points – after just 30 days of using Step One Foods.



Fiber and plant sterol supplements

To see a cholesterol benefit, you need to add at least 10 grams of fiber and 2 grams of plant sterols to your diet, ideally spread out throughout the day. You should take these supplements WITH your meals so that you obtain the most benefit.

Fiber and plant sterol supplementation has been shown to help improve cholesterol levels. However, *the data for improved outcomes is strongest when higher fiber intakes come from dietary transformation rather than from supplements*. Remember that **Step One Foods provides at least 10 grams of whole food fiber and 2 grams of plant sterols in just 2 servings per day**.

By the way, there is no evidence that taking CoQ 10, cayenne, or garlic supplements lowers LDL cholesterol.

Bergamot

Bergamot is a fragrant citrus fruit. The essence from its peel gives Earl Grey tea its distinct flavor.

Bergamot has also been shown to lower cholesterol in small clinical trials. The dose most frequently studied was 1000 mg per day.

Although bergamot is considered relatively safe, it shares some biochemical properties with grapefruit. This means **people on statins should avoid using bergamot due to potential for a toxic interaction**.

Niacin

Niacin, a B vitamin, when taken in high doses, lowers LDL cholesterol. But just because it is a vitamin does not mean it is without side effects when consumed in massive doses.

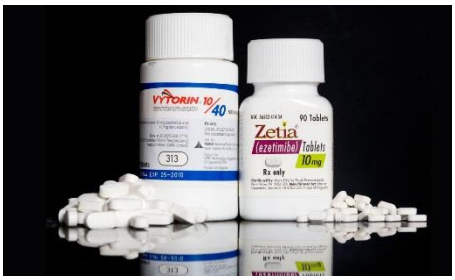
The recommended daily allowance for niacin is around 15-20 mg per day. The amount of niacin prescribed to meaningfully lower LDL cholesterol can be as high as 2000 mg per day.

When you take niacin at those doses, you can develop flushing, itching, digestive issues, liver enzyme abnormalities and muscle side effects. So you need to be monitored as closely as if you were on statin medications.

The form of niacin that is active for cholesterol lowering is nicotinic acid. Nicotinamide, another form of niacin, has no effects on cholesterol levels.

Although niacin has been shown to not only lower LDL cholesterol but also raise HDL (good) cholesterol and lower Triglycerides, the data on improved outcomes (including rates of heart attack and stroke) based on niacin use is less impressive. Nevertheless, this is a reasonable option for people who cannot tolerate statin medications and have exhausted all dietary options.

Note that niacin can worsen blood sugar control. Diabetics should be especially careful about using niacin for cholesterol lowering.



Ezetimibe

Ezetimibe, also known as Zetia®, is a medication that can be added to statins to boost their effects. So, strictly speaking, it's not really a statin substitute, but it does facilitate lower statin dosing – and this is important since statin side effects are more likely the higher the dose.

Zetia® can be taken as a stand-alone prescription medication or can be part of a combination tablet, like Vytorin®, (ezetimibe with simvastatin).

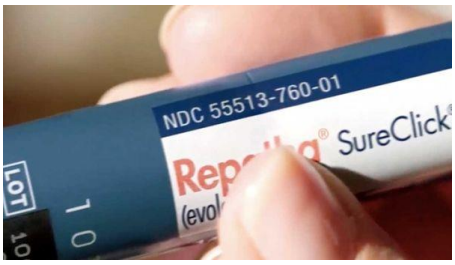
Although adding Zetia® to even a low dose statin can result in profound LDL lowering, the data on outcomes has been less robust, suggesting that it's not only how low you get your LDL level that's important but how you got there that matters too.

This is where Step One Foods fits in again – helping to reduce the dose of statins needed to get to LDL goal. We know that real food has profoundly positive effects on health. **Combining strategic food intake with lower statin doses is therefore a better option than relying on combinations of medications.**

Red yeast rice

Red yeast rice has been shown to lower LDL cholesterol. The reason for this is that red yeast rice contains a compound structurally identical to lovastatin (one of the statin drugs). Because of this, be aware that **red yeast rice can cause the same side effects as statins** and if you take this supplement you should be monitored in the same way as if you were on a prescription cholesterol lowering medication.

The main problem with red yeast rice (above and beyond the fact that it can have the same side effects as statins) is that the supplement industry is not well regulated. Which means the dose of the active ingredient can vary from bottle to bottle and from pill to pill. In addition, other substances can be present in the pill that are not listed or monitored, affecting safety and efficacy.



PCSK9 inhibitors

This is a whole new category of drugs recently approved by the FDA for the treatment of high cholesterol. PCSK9 inhibitors (like Praluent® and Repatha®) are antibodies that lower LDL cholesterol by neutralizing a substance called PCSK9.

PCSK9 is a protein that controls the number of cholesterol receptors in the liver. If PCSK9 levels are lowered, the number of liver cholesterol receptors increases, allowing more LDL to get removed from the blood stream. In other words, if PCSK9 is destroyed by antibodies, LDL levels fall.

Praluent® and Repatha® need to be injected once to twice per month but are extremely effective in lowering LDL (by as much as 70%). They are also **extremely expensive** ($14,000 per patient per year).

Although they appear to be relatively safe, a higher than expected rate of neurologic side effects was reported in the initial clinical trials – especially problems

with memory and general cognition. In addition, long term safety is not yet clear.

Given the cost, insurance companies have been very selective in granting approval for PCSK9 inhibitor use. Many patients find that even when "covered" the associated deductibles can still be prohibitively expensive.

In summary

Some people SHOULD take statins because they have known heart or vascular disease. For others, there are many options for lowering cholesterol that don't involve statin drugs. And even if you do need to take statins, doing everything you can to reduce the dose required to control your cholesterol readings makes sense in order to reduce your risk of developing statin side effects.

Changing diet is the best option because improving nutrition not only helps lower cholesterol levels, but also has wide ranging positive effects on health overall.

Step One Foods was created specifically to help you succeed at changing diet in a way that maximizes your chances of lowering cholesterol naturally. All the foods contain the precise levels of nutrients your body needs to improve heart health and lower cholesterol. Simply replace one meal and one snack each day with Step One Foods and you'll quickly see and feel the results. On average, customers report a 39 point LDL cholesterol reduction in just 30 days.

Try a sample - or take the **30-day challenge** and use promo code **CHALLENGE** to save 15% and help you get started. You'll be happy you did.

How to use Step One Foods to minimize statin dose

If you are thinking of using Step One Foods in the hopes of reducing your reliance on statin medications, here's what you should do:

1. Confirm with your physician that you are in a group of patients for whom it is reasonable to try to reduce statin dose.
2. Get a baseline cholesterol check on your current medication dose.
3. Use Step One Foods twice per day as a substitute for something you are eating already for at least 30 days. You will need 5 boxes of food for every 30 days of use. You can mix and match products as you like.
4. **While still using Step One Foods,** have your profile rechecked 30-60 days after starting the food program.
5. If your cholesterol is stable or improved, cut the statin dose in half and continue to eat Step One Foods twice per day for an additional 30-60 days and repeat instructions #4 and #5.
6. Continue repeating instructions #4 and #5 until you have reached your lowest possible statin dose or you are off the medication altogether.

Even if you can't get off of your statin altogether – or even if you don't see much of a cholesterol improvement with the foods – you will still be making a positive impact on your health with Step One. Remember, heart disease is caused by more than just high cholesterol. Eating better means you are helping to lower blood pressure, lose weight, improve blood sugar control and reduce inflammation inside your body. And all of that adds up to better health regardless of the cholesterol response.

Questions? **866-543-4273**

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