

LIVALO CHALLENGE FACT SHEET: FOR THE DOCTOR

What is the LIVALO Challenge?

The LIVALO Challenge offers patients new to LIVALO an opportunity to try LIVALO for 90 days for as little as \$36*—a cost comparable to that of a generic statin.

To be eligible, your patient must have:

- **Never taken LIVALO before**
- A prescription for a 90-day supply of LIVALO
- Commercial or private insurance, or pay cash

When you're selecting a 2nd-line statin for your adult patients, LIVALO provides proven efficacy, safety, and tolerability¹

In clinical trials versus other commonly prescribed statins, LIVALO demonstrated¹⁻⁴:

- Potent LDL-C reduction up to a mean of 45% at the 4-mg dose[†]
- Reduction of Apo B up to a mean of 37% at the 4-mg dose[†]
- Improvements in other lipid parameters, including Non-HDL-C and TG

LIVALO is a demonstrated safe and tolerable statin¹. In clinical trials:

- ~3% of patients taking LIVALO 4 mg experienced myalgia
- Only 1 in 200 patients discontinued LIVALO 4 mg due to myalgia
- <4% discontinuation rates with LIVALO; not dose dependent

For patients taking multiple medications, LIVALO has a reduced potential for certain drug interactions. Unlike Lipitor® (atorvastatin) and Zocor® (simvastatin), LIVALO is metabolized differently and is not dependent on cytochrome P450 (CYP450).

What happens after my patient completes the 90 days of the LIVALO Challenge?

If you and your patient are satisfied with LIVALO, you can write a new 30-day or 90-day prescription. Your patient's copay will then be as little as **\$18 for a 30-day supply** or **\$54 for a 90-day supply**.

Lipitor is a registered trademark of Pfizer, Inc.
Zocor is a registered trademark of Merck & Co., Inc.

*Based on eligibility, certain rules and restrictions apply.

[†]Based on the mean change from baseline in LDL-C and Apo B observed in three 12-week, randomized, multicenter, double-blind, double-dummy, Phase 3 studies in patients with primary hyperlipidemia or mixed dyslipidemia taking pitavastatin 2 mg and 4 mg.

Important Safety Information for LIVALO® (pitavastatin) tablets

Indications and Usage

LIVALO is a HMG-CoA reductase inhibitor indicated as an adjunctive therapy to diet in:

- Adult patients with primary hyperlipidemia or mixed dyslipidemia to reduce elevated total cholesterol (TC), low-density lipoprotein cholesterol (LDL-C), apolipoprotein B (Apo B), triglycerides (TG), and to increase high-density lipoprotein cholesterol (HDL-C).
- Pediatric patients aged 8 years and older with heterozygous familial hypercholesterolemia (HeFH) to reduce elevated TC, LDL-C, and Apo B.

Important Safety Information for LIVALO® (pitavastatin) tablets (cont)

Limitations of Use

The effect of LIVALO on cardiovascular morbidity and mortality has not been determined.

Contraindications

- Known hypersensitivity to product components.
- Coadministration with cyclosporine.
- Active liver disease, which may include unexplained persistent elevations in hepatic transaminase levels.
- Pregnancy.
- Lactation.

Warnings and Precautions

- **Myopathy and Rhabdomyolysis:** Risk factors include age 65 and greater, renal impairment, inadequately treated hypothyroidism, concomitant use of certain drugs, and higher doses of LIVALO. LIVALO is contraindicated in patients taking cyclosporine and not recommended in patients taking gemfibrozil. The following drugs when used concomitantly with LIVALO may also increase the risk of myopathy and rhabdomyolysis: lipid-modifying dosages of niacin (>1 grams/day), fibrates, and colchicine. Discontinue LIVALO if markedly elevated CK levels occur or myopathy is diagnosed or suspected. Temporarily discontinue LIVALO in patients experiencing an acute or serious condition at high risk of developing renal failure secondary to rhabdomyolysis; e.g., sepsis; shock; severe hypovolemia; major surgery; trauma; severe metabolic, endocrine, or electrolyte disorders; or uncontrolled epilepsy. Inform patients of the risk of myopathy and rhabdomyolysis when starting or increasing the LIVALO dosage. Instruct patients to promptly report any unexplained muscle pain, tenderness or weakness particularly if accompanied by malaise or fever.
- **Immune-Mediated Necrotizing Myopathy (IMNM):** There have been rare reports of IMNM, an autoimmune myopathy, associated with statin use. IMNM is characterized by: proximal muscle weakness and elevated serum creatine kinase, which persist despite discontinuation of statin treatment; muscle biopsy showing necrotizing myopathy without significant inflammation; and improvement with immunosuppressive agents.
- **Hepatic Dysfunction:** Increases in serum transaminases can occur. Rare postmarketing reports of fatal and non-fatal hepatic failure have occurred. Consider liver enzyme testing before initiating therapy and as clinically indicated thereafter. If serious hepatic injury with clinical symptoms and/or hyperbilirubinemia or jaundice occurs, promptly discontinue LIVALO.
- **Increases in HbA1c and Fasting Serum Glucose Levels:** Increases of each have been reported with statins, including LIVALO. Optimize lifestyle measures, including regular exercise, maintaining a healthy body weight, and making healthy food choices.

Adverse Reactions

In short-term controlled studies, the most frequent adverse reactions reported by $\geq 2\%$ of patients treated with LIVALO 1 mg, 2 mg, and 4 mg, respectively, and at a rate \geq placebo were back pain (3.9%, 1.8%, 1.4% vs 2.9%), constipation (3.6%, 1.5%, 2.2% vs 1.9%), diarrhea (2.6%, 1.5%, 1.9% vs 1.9%), myalgia (1.9%, 2.8%, 3.1% vs 1.4%), and pain in extremity (2.3%, 0.6%, 0.9% vs 1.9%). Other serious adverse reactions include rhabdomyolysis, immune-mediated necrotizing myopathy, hepatic dysfunction, and increases in HbA1c and fasting serum glucose. In adult HIV-infected patients with dyslipidemia, the safety profile of LIVALO was generally consistent with that observed in the short-term controlled studies described above. In pediatric patients with HeFH, the safety profile was similar to that observed in the adult population. This is not a complete listing of all reported adverse events.

For additional information please see the full Prescribing Information at www.LivaloHCP.com.

© Kowa Pharmaceuticals America, Inc. (2019) - LIV-RA-0119 PI V-05-2019

References:

1. LIVALO [prescribing information]. Montgomery, AL: Kowa Pharmaceuticals America, Inc.; May 2019.
2. Budinski D, Arneson V, Hounslow N, Gratsiansky N. Pitavastatin compared with atorvastatin in primary hypercholesterolemia or combined dyslipidemia. *Clin Lipidol*. 2009;4(3):291-302.
3. Ose L, Budinski D, Hounslow N, Arneson V. Comparison of pitavastatin with simvastatin in primary hypercholesterolaemia or combined dyslipidaemia [published correction appears in *Curr Med Res Opin*. 2010;26(5):1046]. *Curr Med Res Opin*. 2009;25(11):2755-2764.
4. Stender S, Budinski D, Goshu M, Hounslow N. Pitavastatin shows greater lipid-lowering efficacy over 12 weeks than pravastatin in elderly patients with primary hypercholesterolaemia or combined (mixed) dyslipidaemia. *Eur J Prev Cardiol*. 2013;20(1):40-53.



LIVALO CHALLENGE FACT SHEET: FOR YOU

Your LIVALO Challenge Checklist

If you have complaints about your current statin, it's important to understand that not all statins are the same. LIVALO is a statin that you may be better able to tolerate.

If you are a patient who is new to LIVALO and have commercial insurance, ask your doctor about taking the LIVALO Challenge and use the simple checklist below as your guide.

- Make an appointment with your doctor and bring this LIVALO Challenge Fact Sheet with you. Talk to your doctor about some concerns you may have with your current statin and why you want to try LIVALO.
- Get a prescription for a 90-day supply of LIVALO.
- Get your LIVALO® Challenge Copay Card at livalorx.com/challenge.
- Show your LIVALO® Challenge Copay Card to your pharmacist and pay as little as \$36* for your 90-day supply.
- Be sure to follow up with your doctor as directed.

*Based on eligibility, certain rules and restrictions apply.

Say enough to statin complaints and accept the LIVALO Challenge



IMPORTANT SAFETY INFORMATION FOR LIVALO® (pitavastatin) tablets

Who should NOT take LIVALO?

LIVALO is not right for everyone. Do not take LIVALO if:

- You have a known allergy to LIVALO or any of its ingredients.
- You have active liver problems, including some abnormal liver test results.
- You are nursing, pregnant or may become pregnant, as it may harm the baby.
- You are currently taking cyclosporine or gemfibrozil.

IMPORTANT SAFETY INFORMATION FOR LIVALO® (pitavastatin) tablets (cont)

What is the most important information I should know and talk to my doctor about?

- Call your healthcare provider or get help right away if you experience any symptoms of an allergic reaction, such as rash, itching, or hives.
- Muscle problems may be an early sign of rare, serious conditions. Tell your doctor right away if you have any unexplained muscle pain, weakness, or tenderness, particularly if accompanied by malaise or fever, or if these muscle signs or symptoms persist after discontinuing LIVALO.
- Serious liver problems have been reported rarely in patients taking statins, including LIVALO. Your doctor should do liver tests before you start, and if you have symptoms of liver problems while you are taking LIVALO. Tell your healthcare provider right away if you feel more tired than usual, have a loss of appetite, upper belly pain, dark-colored urine, or yellowing of the skin or eyes.
- Tell your doctor about all your medical conditions and medications you take including nonprescription medicines, vitamins, or herbal supplements.
- Increases in blood sugar levels have been reported with statins, including LIVALO.
- Tell your doctor about your alcohol use.
- Tell your healthcare provider of a known or suspected pregnancy.

What are the most common side effects of LIVALO?

The most common side effects of LIVALO in clinical studies were:

- Back pain
- Constipation
- Diarrhea
- Muscle pain
- Pain in the legs or arms

This is not a complete list of side effects. Talk to your healthcare provider for more information.

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.

How should I store and take LIVALO?

- Store LIVALO tablets at room temperature, in a dry place, and out of the reach of children.
- Take LIVALO orally once daily with or without food at the same time each day.
- Swallow the tablet whole. Do not split, crush, dissolve, or chew.
- The maximum recommended dosage is LIVALO 4 mg once daily.

Other important information I should know about LIVALO.

- LIVALO has not been studied to evaluate its effect on reducing heart-related disease or death.
- LIVALO is available by prescription only.

For additional information, please see the full Prescribing Information at LivaloRx.com.

© Kowa Pharmaceuticals America, Inc. (2019) - LIV-RA-0120 PI of 05/2019

LIVALO is a registered trademark of the Kowa group of companies.

© Kowa Pharmaceuticals America, Inc. (2019)

All rights reserved. LIV-MT-3574 July 2019

