



## LIVALO<sup>®</sup> (pitavastatin) Fact Sheet for Media

### What is LIVALO?

LIVALO is a statin approved by the U.S. Food and Drug Administration (FDA) for use as an adjunctive therapy to diet to reduce elevated total cholesterol, low-density lipoprotein cholesterol (LDL-C), apolipoprotein B, triglycerides, and to increase high density lipoprotein cholesterol (HDL-C) in adult patients with primary hyperlipidemia or mixed dyslipidemia.<sup>1</sup>

### What Makes LIVALO Different From Other Statins?

While few drugs, including LIVALO, are free from drug-drug interactions, LIVALO may be an attractive option for physicians treating patients on multiple medications metabolized through the cytochrome P450 system. This is because LIVALO is only minimally metabolized by the cytochrome P450 system, which may help reduce its potential for drug-drug interactions mediated by this system. The cytochrome P450 system is involved in approximately 75% of all drug metabolism.<sup>2</sup>

Please review the LIVALO [Important Safety Information](#) and [Full Prescribing Information](#) to learn more about other important drug interactions noted with LIVALO.

### How Effective Is LIVALO?

The efficacy of LIVALO has been evaluated in non-inferiority studies against atorvastatin, simvastatin, and pravastatin in patients with primary hyperlipidemia or mixed dyslipidemia. LIVALO was evaluated in patients with primary hyperlipidemia or mixed dyslipidemia and including those with at least two additional risk factors for coronary heart disease as well as in patients with Type II diabetes and patients 65 years and over.

Among these studies, LIVALO was shown to lower LDL-C- up to 39% at a 2 mg dose and up to 45% at a 4 mg dose. In addition to lowering LDL-C, LIVALO was shown to also reduce total cholesterol, triglycerides, apolipoprotein B, and to increase HDL-C.

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<sup>1</sup> LIVALO [prescribing information] Montgomery, AL; Kowa Pharmaceuticals America, Inc.

<sup>2</sup> Guengerich FP. Cytochrome P450 and chemical toxicology. *Chem Res Toxicol.* 2008;21(1):70-83

## What is the Safety Profile of LIVALO?

The most common side effects of LIVALO in clinical studies were back pain, constipation, diarrhea, muscle pain, and pain in the legs or arms.<sup>3,4</sup>

The approval of LIVALO was based on 10 clinical trials up to 12-weeks in duration and four subsequent extensions of these trials up to 60-weeks.<sup>5</sup> These trials included five 12-week comparative efficacy and safety studies with three currently FDA-approved statins: atorvastatin, simvastatin, and pravastatin.

Please see the [Important Safety Information](#) and [Full Prescribing Information](#) of LIVALO for additional safety information.

## How Is LIVALO Taken?

LIVALO may be taken at any time of day, with or without food.<sup>6</sup>

The usual recommended starting dose is 2 mg, with a maximum dose of 4 mg. The starting dose and maintenance doses of LIVALO should be individualized according to patient characteristics, such as goal of therapy and response.

Please see the [Full Prescribing Information](#) for specific details regarding dosing.

## IMPORTANT SAFETY INFORMATION

- LIVALO is not right for everyone, including those who previously have had an allergic reaction to LIVALO, anyone with liver problems, patients with severe kidney disease not yet on hemodialysis, or women who are nursing, pregnant, or who may become pregnant.
- Do not take LIVALO if you are taking cyclosporine.
- If you take LIVALO, tell your doctor right away if you experience any unexplained muscle pain, tenderness (soreness), or weakness, particularly if accompanied by fever or malaise (a general feeling of discomfort). This could be a sign of a rare but serious side effect.
- It is recommended that your doctor do blood tests to monitor your liver function before starting LIVALO, and then at 12 weeks following the start of LIVALO, after any increase in dose, and periodically (e.g., every 6 months) thereafter.

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<sup>3</sup> Budinski D, Arneson V, Hounslow N, Gratsiansky N. Pitavastatin compared with atorvastatin in primary hypercholesterolemia or combined dyslipidemia. *Clinical Lipidol.* 2009; Vol. 4(3):291-302

<sup>4</sup> 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

<sup>5</sup> Ose L, Budinski D, Hounslow N, Arneson V. Long-term treatment with pitavastatin is effective and well tolerated by patients with primary hypercholesterolemia or combined dyslipidemia [published correction appears in *Atherosclerosis.* 2010;212(2):704]. *Atherosclerosis.* 2010;210(1):202-208.

<sup>6</sup> LIVALO [prescribing information] Montgomery, AL; Kowa Pharmaceuticals America, Inc.

- The most common side effects of LIVALO in clinical studies were muscle pain, back pain, constipation, diarrhea, and pain in the legs or arms. This is not a complete list of side effects.
- LIVALO has not been studied to understand its effect on reducing heart-related disease or death.
- Tell your doctor about all the medications you take, including nonprescription medicines, vitamins, or herbal supplements.

For more information about LIVALO, please see the [Full Prescribing Information](http://www.livalorx.com/documents/LIVALOpitavastatinprescribinginformationV1_220100131.pdf) at ([http://www.livalorx.com/documents/LIVALOpitavastatinprescribinginformationV1\\_220100131.pdf](http://www.livalorx.com/documents/LIVALOpitavastatinprescribinginformationV1_220100131.pdf)). You may also learn more about LIVALO at [www.LivaloRx.com](http://www.LivaloRx.com).

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LIV-MT-0037 PS67723