

**What is LIVALO?**



LIVALO is a statin approved by the U.S. Food and Drug Administration (FDA) for use in addition to diet to reduce total cholesterol, low density lipoprotein cholesterol (LDL-C), triglycerides (TG), apolipoprotein B (Apo B), 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. 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>

LIVALO cannot be taken with cyclosporine. Please review the LIVALO Important Safety Information and Prescribing Information to learn more about other important drug interactions noted with LIVALO.

**How Effective Is LIVALO?**

The efficacy of LIVALO has been evaluated against atorvastatin, simvastatin, and pravastatin in patients with primary hyperlipidemia or mixed dyslipidemia. In phase III studies, LIVALO was evaluated in patients with Type II diabetes, patients 65 years and over, and patients with two or more risk factors for coronary heart disease.

Among these studies, LIVALO has been 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 has been shown to also reduce total cholesterol, triglycerides, Apo B, and to increase HDL-cholesterol.

**What is the Safety Profile of LIVALO?**

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. These trials included five 12-week comparative efficacy and safety studies with three currently FDA-approved statins: atorvastatin, simvastatin, and pravastatin.

LIVALO has been available to patients in Asia since 2003.<sup>3</sup>

The most common side effects of LIVALO in clinical studies were muscle pain, back pain, constipation, diarrhea and pain in the legs or arms.<sup>4,5</sup> Please review the Important Safety Information and 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.

A 1 mg dose is available for use in specific populations or when using LIVALO in combination with certain drugs. Please see the Full Prescribing Information for specific details regarding dosing.

**LIVALO Important Safety Information**

LIVALO is not right for everyone, including, patients who previously have had an allergic reaction to LIVALO or any of its components, anyone with active liver problems, those with severe kidney disease not yet on hemodialysis, or women who are nursing, pregnant or who may become pregnant.

Patients should not take LIVALO if they are taking cyclosporine.

Patients taking LIVALO should tell their doctor immediately if they experience any unexplained muscle pain, tenderness or weakness, particularly if accompanied by fever or a general feeling of discomfort. This could be a sign of a rare but serious side effect.

It is recommended that physicians conduct blood tests to monitor patient's liver function before starting LIVALO, at 12 weeks following the start of LIVALO or after any increase in dose and then periodically (e.g., every six months) thereafter.

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 in reducing heart-related disease or death.

Patients should tell their doctor about all the medications they take, including all prescription and nonprescription medicines, vitamins or herbal supplements.

For more information about LIVALO, please see the Full Prescribing Information 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).

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

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<sup>1</sup> LIVALO prescribing information

<sup>2</sup> F. Peter Guengerich. Cytochrome P450 and Chemical Toxicology. Chem. Res. Toxicol. 2008, 21, 70-83

<sup>3</sup> LIVALO prescribing information

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

<sup>5</sup> Ose L, Budinski D, Hounslow N, Arneson V. Comparison of pitavastatin with simvastatin in primary hypercholesterolaemia or combined dyslipidaemia. *Curr Med Res Opin.* 2009 Nov;25(11):2755-64

<sup>6</sup> LIVALO prescribing information