Please review the LIVALO Important Safety Information and full Prescribing Information to learn more about LIVALO.

### LIVALO® (pitavastatin) Frequently Asked Questions

**What is LIVALO?**

LIVALO is a prescription medicine that, along with diet, has been approved for the treatment of high cholesterol. LIVALO has not been studied to evaluate its effect on reducing heart-related disease or death.¹

LIVALO works by blocking a certain protein known as an “enzyme” that controls how much cholesterol the body makes. Because of this, LDL “bad” cholesterol can be reduced, while HDL “good” cholesterol can be increased.¹,²

**Who should NOT take LIVALO?**

LIVALO is not right for everyone, including those who have had an allergic reaction to LIVALO, anyone with active liver disease, women who are nursing, pregnant, or who may become pregnant and anyone currently taking cyclosporine or gemfibrozil.¹

**What’s Important about the Metabolism of LIVALO?**

Patients with high cholesterol might be aware that cholesterol is made in the liver. But they may not know that approximately 75% of all drugs processed in the body share a common metabolic pathway in the liver.³ When drugs that share this pathway are taken together, a drug interaction may occur. LIVALO is minimally dependent on this common metabolic pathway and may be less likely to interact with drugs that depend on this pathway.¹,⁴,⁵

Please be aware of the following drug interaction considerations with LIVALO:¹

- If patients are taking cyclosporine, they should not take LIVALO.
- Caution should be taken when using LIVALO in combination with other cholesterol drugs like niacin and fibrates, as this may increase a patient’s risk of serious muscle problems.
- Some drugs, like erythromycin and rifampin, may lead to drug interactions requiring a lower maximum daily dose of LIVALO, when used in combination.

**How Effective Is LIVALO?**

LIVALO offers LDL-C reductions of up to 45% at the maximum dose of 4 mg. This data is based on the mean % change from baseline in LDL-C observed in 3, 12-week, double-blind, non-inferiority Phase 3 studies in patients with primary hyperlipidemia or mixed dyslipidemia taking LIVALO 2 mg (-38, -39, -39) and 4 mg (-45, -44, -44).¹
Please review the LIVALO Important Safety Information and full Prescribing Information to learn more about LIVALO.

<table>
<thead>
<tr>
<th>Study</th>
<th>LDL-C</th>
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<td>2 mg</td>
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<td>301</td>
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*Mean % change from baseline.

†Study Descriptions:¹
Three 12-week, randomized, multicenter, double-blind, double-dummy, Phase 3 studies in patients with primary hyperlipidemia or mixed dyslipidemia: **Study 301**: LIVALO 2 mg (n=315) and 4 mg (n=298); **Study 302**: LIVALO 2 mg (n=307) and 4 mg (n=319); **Study 306**: in patients ≥ 65 years, LIVALO 1 mg (n=207), 2 mg (n=224), and 4 mg (n=210).

What are the most common side effects of LIVALO?¹
The most common side effects of LIVALO in clinical studies were:

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

How Should Patients Take LIVALO?¹

- Take LIVALO once a day, every day, with or without food, as long as prescribed by a doctor.
- The doctor should do blood tests to check cholesterol levels before and during treatment with LIVALO. The dose of LIVALO may be changed based on these blood test results.
- If a patient misses a dose of LIVALO, take it as soon as possible, unless it is almost time for the next dose. Do not take double doses. Do not take more than 4 mg once daily.
- It is important to tell one's doctor about all the medicines a patient takes, including nonprescription medicines, vitamins, or herbal supplements.

LIVALO is available in 1-mg, 2-mg, and 4-mg tablets.¹
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.

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.

What are the most common side effects of LIVALO?
The most common side effects of LIVALO in clinical studies were:
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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 all 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.
• LIVALO can be taken at any time of day, with or without food.
• Swallow the tablet whole. Do not split, crush, dissolve, or chew.

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.

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References

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