

ORBALIP[®] 10, 20 and 40MG (ATORVASTATIN)

What is ORBALIP[®]?

Atorvastatin is an HMG CoA reductase inhibitor. Atorvastatin blocks the production of cholesterol (a type of fat) in the body.

Atorvastatin is used to reduce the amounts of LDL (bad) cholesterol, total cholesterol, triglycerides (another type of fat), and apolipoprotein B (a protein needed to make cholesterol) in your blood. Atorvastatin is also used to increase the level of HDL (good) cholesterol in your blood. These actions are important in reducing the risk of hardening of the arteries, which can lead to heart attacks, stroke, and peripheral vascular disease.

What is the most important information I should know about ORBALIP[®] Tablet?

Rare cases of muscle problems and liver problems have been associated with the use of atorvastatin and other similar medicines. Contact your doctor immediately if you experience unexplained muscle pain, tenderness, or weakness, especially if accompanied by a fever or flu-like symptoms or yellowing of the skin or eyes, abdominal pain, unexplained fatigue, dark colored urine or pale colored stools. These may be early symptoms of muscle or liver problems. Do not take atorvastatin without first talking to your doctor if you have liver disease. Alcohol and atorvastatin can both be damaging to the liver. Alcohol should be used only in moderation. Discuss the use of alcohol with your doctor so that the potential for liver problems can be determined. Do not take atorvastatin if you are pregnant, could become pregnant during treatment, or if you are breast-feeding a baby.

What should I discuss with my healthcare provider before taking ORBALIP[®] Tablet?

Do not take Orbalip[®] without first talking to your doctor if you have liver disease. Before taking Orbalip[®], tell your doctor if you drink alcoholic beverages, have a chronic muscular disease, require major surgery, or have a blood disorder. You may not be able to take Orbalip[®], or you may require a dosage adjustment or special monitoring during treatment if you have any of the conditions listed above. This means that atorvastatin is known to cause birth defects if it is taken during pregnancy. Do not take Orbalip[®] if you are pregnant or could become pregnant during treatment. It is not known whether atorvastatin passes into breast milk. Do not take this medication without first talking to your doctor if you are breast-feeding a baby.

How should I take ORBALIP[®] Tablet?

Take Orbalip[®] exactly as directed by your doctor. If you do not understand these directions, ask your pharmacist, nurse, or doctor to explain them to you.

Take each dose with a full glass of water.

Orbalip[®] can be taken with or without food.

Orbalip[®] is usually taken once a day. Try to take your dose at the same time each day. Follow your doctor's instructions.

Your doctor may want to monitor your liver function with blood tests before starting treatment with Orbalip[®], at twelve weeks after both the start of your treatment and any increase in dose, and periodically (every 6 months) thereafter. Depending on the results of these tests, your doctor can determine how much monitoring you will require.

Grapefruit and grapefruit juice may interact with atorvastatin. The interaction could lead to potentially dangerous effects. Discuss the use of grapefruit and grapefruit juice with your doctor. Do not increase or decrease the amount of grapefruit products in your diet without first talking to your doctor.

Eat a low-fat, low-cholesterol diet. To realize beneficial effects from Orbalip[®], avoid fatty, high-cholesterol foods.

It is important to take Orbalip[®] regularly to get the most benefit.

Do not stop taking Orbalip[®] without first talking to your doctor. Orbalip[®] may need to be taken on a long-term basis for the treatment of high cholesterol.

Your doctor may want you to have blood tests or other medical evaluations during treatment with Orbalip[®] to monitor progress and side effects.

Store Orbalip[®] at room temperature away from moisture and heat.

What happens if I miss a dose?

Take the missed dose as soon as you remember. However, if it is almost time for the next dose, skip the missed dose and take only the next regularly scheduled dose. Do not take a double dose of this medication.

What happens if I overdose?

Seek emergency medical attention if an overdose is suspected. The symptoms of an atorvastatin overdose are not known.

What should I avoid while taking ORBALIP[®] Tablet?

Alcohol and atorvastatin can both be damaging to the liver. Alcohol should be used only in moderation. Discuss the use of alcohol with your doctor so that the potential for liver problems can be determined.

Grapefruit and grapefruit juice may interact with atorvastatin. The interaction could lead to potentially dangerous effects. Discuss the use of grapefruit and grapefruit juice with your doctor. Do not increase or decrease the amount of grapefruit products in your diet without first talking to your doctor.

ORBALIP[®] Tablet side effects

Rare cases of muscle problems and liver problems have been associated with the use of Orbalip[®] and other similar medicines. Contact your doctor immediately if you experience unexplained muscle pain, tenderness, or weakness, especially if accompanied by a fever or flu-like symptoms or yellowing of the skin or eyes, abdominal pain, unexplained fatigue, dark colored urine or pale colored stools. These may be early symptoms of muscle or liver problems. If you experience any of the following serious side effects, stop taking Orbalip[®] and seek emergency medical attention or contact your doctor immediately: an allergic reaction (difficulty breathing; closing of the throat; swelling of the lips, tongue, or face; or hives); decreased urine or rust-colored urine; or blurred vision.

Other, less serious side effects may be more likely to occur. Continue to take Orbalip[®] and talk to your doctor if you experience headache; upset stomach or flatulence; or a rash.

Side effects other than those listed here may also occur. Talk to your doctor about any side effect that seems unusual or that is especially bothersome.

What other drugs will affect ORBALIP[®] Tablet?

Do not take Orbalip[®] without first talking to your doctor if you are taking any of the following medicines: cyclosporine (Sandimmune, Neoral); gemfibrozil (Lopid), clofibrate (Atromid-S), or fenofibrate (Tricor); niacin (Nicolar, Nicobid, Slo-Niacin, others); erythromycin (E-Mycin, E.E.S., Ery-Tab, others) or clarithromycin (Biaxin); cholestyramine (Questran) or colestipol (Colestid); hormonal birth control (pills, patches, or implants); or an antifungal medication such as itraconazole (Sporanox), fluconazole (Diflucan), or ketoconazole (Nizoral).

You may not be able to take Orbalip[®], or you may require a dosage adjustment or special monitoring during treatment if you are taking any of the medicines listed above.

Drugs other than those listed here may also interact with Orbalip[®]. Talk to your doctor and pharmacist before taking any prescription or over-the-counter medicines, including vitamins, minerals, and herbal products.

What does my medication look like?

Atorvastatin is available with a prescription under the brand name Orbalip[®] 10mg, 20mg and 40mg per tablet in packs of 30 tablets.

Remember, keep this and all other medicines out of the reach of children, never share your medicines with others, and use this medication only for the indication prescribed.