





**GENERIC NAME:** pravastatin

#### **DRUG CLASS AND MECHANISM**

Pravastatin is an oral drug for lowering cholesterol in the blood. It has been shown to reduce the occurrence of heart attacks, strokes and death caused by coronary heart disease. It belongs to a class of drugs called HMG-CoA reductase Inhibitors, commonly called "statins". Other statins include simvastatin (Zocor), lovastatin (Mevacor), atorvastatin (Lipitor) and fluvastatin (Lescol). Statins reduce cholesterol by inhibiting an enzyme in the liver (HMG-CoA reductase) that is necessary for the production of cholesterol. In the blood, statins lower total and LDL ("bad") cholesterol as well as triglycerides. They also increase HDL ("good") cholesterol. LDL cholesterol is believed to be an important cause of coronary artery disease. Lowering LDL cholesterol levels slows and may even reverse coronary artery disease. Raising HDL cholesterol levels also may slow coronary artery disease.

Scientists have discovered that inflammation of the coronary arteries also may contribute to coronary heart disease. Inflammation is associated with elevated levels of a protein called C-reactive protein. This C-reactive protein in blood can be measured by a test, referred to as the "highly sensitive" C-reactive protein test (Hs-CRP). Elevated levels of Hs-CRP predict the occurrence of heart attacks, strokes and death. In fact, Hs-CRP is a better predictor of heart attacks, strokes and death than cholesterol levels. Pravastatin reduces the levels of Hs-CRP and it has been suggested that pravastatin may reduce coronary artery disease by reducing inflammation rather than, or in addition to, lowering levels of cholesterol. Pravastatin was approved by the FDA in October 1991.

PRESCRIPTION: Yes

**GENERIC AVAILABLE: No** 

PREPARATIONS: Tablets: 10, 20, 40, and 80 mg

#### PRESCRIBED FOR

**Pravastatin** is used for the reduction of total and LDL cholesterol as well as triglycerides and to increase HDL cholesterol. Pravastatin reduces the occurrence of heart attacks, strokes and death caused by coronary artery disease

## DOSING

The starting dose for most adults is 40 mg once daily. The maximum dose is 80 mg per day.

### **DRUG INTERACTIONS**

Bile acid sequestrants such as cholestyramine (Questran) may significantly reduce the absorption of pravastatin and therefore reduce its effect. Therefore, **pravastatin** should be taken 1-4 hours after bile acid sequestrants.

The use of **pravastatin** with nicotinic acid, gemfibrozil (Lopid) or other drugs that may cause liver or muscle problems may increase the incidence of such side effects.

### USES

**Pravastatin** is an enzyme blocker (HMG-CoA reductase inhibitor), also known as a "statin". It is used in adults and children (8 years of age and older), along with a proper diet, to help lower cholesterol and fats (triglycerides) in the blood. In general, this drug is prescribed after non-drug treatment options have not been fully successful at lowering cholesterol (e.g., diet change, increase in exercise, weight loss if overweight). Reducing cholesterol and triglycerides help prevent strokes and heart attacks.

#### **HOW TO USE**

Take this medication by mouth usually once daily, with or without food, or as directed by your doctor. This drug is best taken in the evening. Dosage is based on your medical condition, response to therapy, and use of certain interacting medicines. Many of the drugs listed in the Drug Interactions section may increase the chances of muscle injury when used with pravastatin. Consult your doctor or pharmacist for more details. If you also take certain other drugs to lower your cholesterol (bile acid-binding resins such as cholestyramine or colestipol), take pravastatin at least 1 hour before or 4 hours after these drugs. Use this medication regularly in order to get the most benefit from it. Remember to use it at the same time each day. It may take up to 4 weeks before the full benefit of this drug takes effect. It is important to continue taking this medication even if you feel well. Most people with high cholesterol or triglycerides do not feel sick.

#### SIDE EFFECTS

Heartburn, headache, or dizziness may occur. If any of these effects persist or worsen, notify your doctor or pharmacist promptly. This drug may infrequently cause muscle damage (which can rarely lead to a very serious, possibly fatal, condition called rhabdomyolysis). Seek immediate medical attention if you develop: muscle pain/tenderness/weakness (especially with fever or unusual tiredness). Tell your doctor immediately if any of these highly unlikely but very serious side effects occur: yellowing eyes and skin, dark urine, severe fatigue, severe stomach/abdominal pain, persistent nausea, change in the amount of urine. A serious allergic reaction to this drug is unlikely, but seek immediate medical attention if it occurs. Symptoms of a serious allergic reaction include: rash, itching, swelling, severe dizziness, trouble breathing. If you notice other effects not listed above, contact your doctor or pharmacist.

#### **PRECAUTIONS**

Before taking pravastatin, tell your doctor or pharmacist if you are allergic to it; or to other "statins"; or if you have any other allergies. This medication should not be used if you have certain medical conditions. Before using this medicine. consult your doctor or pharmacist if you have: active liver disease. Before using this medication, tell your doctor or pharmacist your medical history, especially of: heart disease, history of liver disease, kidney disease, underactive thyroid (hypothyroidism), diabetes (poorly controlled), alcohol use. The rare development of severe muscle damage (see Side Effects) can infrequently lead to serious kidney problems. This medication is usually temporarily stopped if you have any condition which can increase your risk of developing kidney problems. Before stopping your medication, notify your doctor immediately if you have any of the following conditions: major surgery, trauma, serious illness (e.g., sepsis, severe metabolic/endocrine/electrolyte disorders), very low blood pressure, uncontrolled seizures. This drug may make you dizzy; use caution engaging in activities requiring alertness such as driving or using machinery. Limit alcoholic beverages. Daily use of alcohol may increase your chance for serious side effects. Caution is advised when using this drug in the elderly because they may be more sensitive to the side effects of the drug, especially muscle damage. This medication must not be used during pregnancy. If you become pregnant or think you may be pregnant, inform your doctor immediately. It is recommended that young girls and women of child-bearing age use effective birth control measures to prevent pregnancy while taking this drug since pravastatin may cause fetal harm. A small amount of this drug passes into breast milk and may have undesirable effects on a nursing infant. Breastfeeding is not recommended while using this drug. Consult your doctor before breast-feeding.

## **OVERDOSE**

If overdose is suspected, contact your local poison control center or emergency room immediately. US residents can call the US national poison hotline at 1-800-222-1222. Canadian residents should call their local poison control center directly.

#### MISSED DOSE

If you miss a dose, use it as soon as you remember. If it is near the time of the next dose, skip the missed dose and resume your usual dosing schedule. Do not double the dose to catch up.

#### STORAGE

Store at room temperature at 77 degrees F (25 degrees C) away from light and moisture. Brief storage between 59 and 86 degrees F (15 to 30 degrees C) is permitted. Do not store in the bathroom. Keep all medicines away from children and pets.

**Note :** This product information is intended only for residents of the India. Taj Pharmaceuticals Limited, medicines help to treat and prevent a range of conditions—from the most common to the most challenging—for people around the world.



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