

# Product X

## Pravastatin Tablets

### Patient Information About Product X

#### MODE OF ACTION

PRODUCT X is a cholesterol-lowering drug used to help prevent a first heart attack, reduce the risk of death from heart disease and reduce the risk of heart surgery in patients with high cholesterol but no symptoms or history of heart disease.

#### CONTRAINDICATIONS

Hypersensitivity to any component of this medication or other HMG-CoA reductase inhibitors. Active liver disease or unexplained persistent elevations in liver enzymes. A history of heavy alcohol ingestion.

**Pregnancy:** Pravastatin should be administered to women of child-bearing age only when such patients are highly unlikely to conceive and have been informed of the potential hazards to the fetus. If the patient becomes pregnant while taking this drug, therapy should be discontinued.

**Nursing mothers:** A small amount of pravastatin is excreted in human breast milk. Because of the potential adverse reactions in nursing infants, women taking PRODUCT X should not nurse.

**Pediatric use:** Safety and effectiveness in individuals less than 18 years old have not been established. Hence treatment is not recommended at this time.

#### WARNINGS

HMG-CoA reductase inhibitors, like some other lipid-lowering therapies, have been associated with biochemical abnormalities of liver function. It is recommended that liver function tests be performed before the initiation of treatment, at 6 and 12 weeks after initiation of therapy or elevation in dose and periodically thereafter. Patients who develop increased transaminase levels should be monitored with a second liver function evaluation. Should an increase in serum transaminase values of three times the upper limit of normal persist, withdrawal of pravastatin therapy is recommended.

**Skeletal Muscle:** Rare cases of rhabdomyolysis with acute renal failure secondary to myoglobinuria have been reported with pravastatin and other drugs in this class. Uncomplicated myalgia has also been reported in pravastatin-treated patients. Myopathy was rare in pravastatin clinical trials. Myopathy should be considered in any patient with diffuse myalgias, muscle tenderness or weakness and/or marked elevation of creatine phosphokinase (CPK).

#### ADVERSE REACTIONS

Pravastatin is generally well tolerated. The following effects have been reported with other drugs in this class. However, not all the effects listed below have necessarily been associated with pravastatin therapy.

**Skeletal:** myopathy, rhabdomyolysis, arthralgia.

**Neurological:** dysfunction of certain cranial nerves, tremor, vertigo, memory loss, paresthesia, peripheral neuropathy, peripheral nerve palsy, anxiety, insomnia, depression.

**Hypersensitivity reactions:** an apparent hypersensitivity syndrome has been reported rarely, which has included one or more of the following features: anaphylaxis, angioedema, lupus erythematosus-like syndrome, urticaria, purpura, photosensitivity, fever, chills, malaise, dyspnea, erythema multiforme.

**Gastrointestinal:** pancreatitis, hepatitis, cholestatic jaundice, fatty change in liver and rarely cirrhosis, fulminant hepatic necrosis, hepatoma, anorexia, vomiting.

**Reproductive:** gynecomastia, loss of libido, erectile dysfunction.