

PACKAGE LEAFLET: INFORMATION FOR THE USER

Pravastatin sodium 10 mg, 20 mg, and 40 mg tablets pravastatin

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any side effects not listed in this leaflet. See section 4.

What is in this leaflet

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1. What Pravastatin is and what it is used for

Pravastatin belongs to a group of drugs called HMG-CoA reductase inhibitors. These reduce the amount of cholesterol and triglycerides (fatty substances) in your blood.

Pravastatin is used:

- to reduce your risk in the future of developing coronary heart disease or having a heart attack or stroke, if you have raised levels of cholesterol but do not have coronary heart disease
- to reduce your risk of having a further heart attack or stroke, if you have already had a heart attack or have unstable angina
- to reduce increased lipid levels, if you have had an organ transplant and are taking medication to stop your body rejecting the transplant.

Some further information:

- While cholesterol is vital for the normal functioning of the body, if the level in the blood becomes too high it can build up on the walls of the arteries. Eventually blood vessels can become blocked. Only a small amount of cholesterol comes from our diet, the majority is made by our own livers. The body produces most cholesterol at night.
- Even though you may be on a low fat diet, your doctor has done some blood tests which show that you still have too much fat (including cholesterol) in your blood. A high cholesterol level is generally recognised as adding to the risk of heart disease. Additional factors such as existing heart disease, high blood pressure, diabetes, being overweight, lack of exercise and smoking can also greatly increase the risk of the development or progression of heart disease.

2. What you need to know before you take Pravastatin

Do not take Pravastatin:

- If you are allergic to pravastatin or any of the other ingredients of this medicine (listed in section 6)
- have current liver problems
- are pregnant or there is a possibility that you may become pregnant or are breast-feeding.

- If you are taking or, in the last 7 days, have taken or been given a medicine called fusidic acid (used to treat bacterial infection).

Warnings and precautions

Tell your doctor before you start to take this medicine if you:

- have kidney problems
- are over 70 years of age
- have suffered with liver problems in the past
- have an underactive thyroid gland
- have a hereditary muscle disorder or a family history of such problems
- have previously suffered from side effects affecting your muscles when taking another cholesterol lowering medicine such as a statin or a fibrate e.g. gemfibrozil
- have problems with alcohol abuse (regularly drinking large amounts of alcohol)
- have severe respiratory failure.
- are taking or have taken in the last 7 days a medicine called fusidic acid, (a medicine for bacterial infection) orally or by injection. The combination of fusidic acid and Pravastatin can lead to serious muscle problems (rhabdomyolysis).
- have or have had myasthenia (a disease with general muscle weakness including in some cases muscles used when breathing), or ocular myasthenia (a disease causing eye muscle weakness) as statins may sometimes aggravate the condition or lead to the occurrence of myasthenia (see section 4).

If you have suffered from any of these problems, your doctor will need to carry out a blood test before and possibly during Pravastatin treatment to assess your risk of developing muscle-related side effects.

Also tell your doctor or pharmacist if you have a muscle weakness that is constant. Additional tests and medicines may be needed to diagnose and treat this.

While you are on this medicine your doctor will monitor you closely if you have diabetes or at risk of developing diabetes. You are likely to be at risk of developing diabetes if you have high levels of sugars and fats in your blood, are overweight and have high blood pressure.

Your doctor should do a blood test before you start taking Pravastatin and if you have any symptoms of liver problems while you take Pravastatin. This is to check how well your liver is working. Your doctor may also want you to have blood tests to check how well your liver is working after you start taking Pravastatin.

Other medicines and Pravastatin

Talk to your doctor if you are taking any of the following:

- a group of cholesterol-lowering medicines called fibrates e.g. fenofibrate or gemfibrozil
- cyclosporin (an immunosuppressant used after an organ transplant), as these medicines can interfere with the way pravastatin works in your body
- drugs known as bile acid sequestrants (a class of drugs that prevents bile acids being reabsorbed from the digestive system, so promoting conversion of cholesterol into bile acids) e.g. cholestyramine, colestipol (please see section 3, If you are also taking a bile acid sequestrant)
- the antibiotics erythromycin, clarithromycin or fusidic acid. Do not take fusidic acid while using this medicine. Also see section 4 of this leaflet.

If you are taking a drug used to treat and prevent formation of blood clots called “vitamin K antagonist”, tell your doctor before taking Pravastatin because the use of vitamin K antagonists concomitantly with Pravastatin might increase the results of blood tests used to monitor the treatment with vitamin K antagonists.

Taking Pravastatin with any of these medicines can increase the risk of muscle problems:

- Colchicine (used to treat gout).
- Nicotinic acid (used to treat high blood cholesterol).
- Rifampicine (used to treat an infection called tuberculosis)
- Lenalidomide (used to treat a type of blood cancer called multiple myeloma)

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

- If you need to take oral fusidic acid to treat a bacterial infection you will need to temporarily stop using this medicine. Your doctor will tell you when it is safe to restart Pravastatin. Taking Pravastatin with fusidic acid may rarely lead to muscle weakness, tenderness or pain (rhabdomyolysis). See more information regarding rhabdomyolysis in section 4.

Pravastatin with alcohol

- Keep alcohol intake to a minimum, if you want to drink then only have small quantities of alcohol whilst taking this medicine, and make sure you do not stop taking your medicine if you have an alcoholic drink one evening.

Pregnancy and breast-feeding

DO NOT take Pravastatin:

- if you are pregnant or breast-feeding, or if you are planning to become pregnant
- if you are a woman who could become pregnant (unless you are using a reliable form of contraception other than the pill or other hormonal contraceptives). If you do become pregnant when taking Pravastatin, stop taking the tablets as soon as you become aware of it.

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

- Pravastatin may cause dizziness or visual disturbances, if affected do not drive or operate machinery.

Pravastatin contains lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

Pravastatin contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per film-coated tablet, that is to say essentially 'sodium-free'.

3. How to take Pravastatin

Always take this medicine exactly as your doctor has told you. Check with your doctor if you are not sure. Your doctor will explain the importance of a low fat diet as well as taking Pravastatin.

The tablets should be swallowed preferably with a glass of water. Pravastatin can be taken with or without food.

Adults (including the elderly)

- The usual dose is 10 – 40 mg once a day, preferably in the evening.
- **Following organ transplantation**
- The usual dose is 20 mg.
- **If you are also taking a bile acid sequestrant**, such as cholestyramine or colestipol, Pravastatin should be taken at least one hour before or four hours after you have taken the bile acid sequestrant. This is because the absorption of Pravastatin can be affected by these medicines if taken too closely together.

Liver or kidney problems

If you have either liver or kidney problems your doctor may prescribe a lower dose.

Use in children and adolescents

- The usual dose is 10 – 20 mg once daily between 8 and 13 years of age and 10 – 40 mg daily between 14 and 18 years of age.

If you take more Pravastatin than you should

If you (or someone else) swallow a lot of the tablets all at once, or if you think a child has swallowed any of the tablets, contact your nearest hospital casualty department or your doctor immediately. Please take this leaflet, any remaining tablets, and the container with you to the hospital or doctor so that they know which tablets were consumed.

If you forget to take Pravastatin

If you forget to take a dose, take one as soon as you remember, unless it is nearly time to take the next one. Do not take a double dose to make up for a forgotten dose.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, Pravastatin can cause side effects, although not everybody gets them.

Stop taking the tablets and tell your doctor immediately, or go to the casualty department at your nearest hospital if any of the following happen:

- an **allergic reaction** causing swelling of the face or neck, muscle and joint pain, hives, fever, flushing, shortness of breath. This is a very serious but rare side effect. You may need urgent medical attention or hospitalisation.
- you develop any **unexplained or persistent muscle pain**, tenderness, weakness or cramps, especially if at the same time you feel unwell or have a high temperature. In very rare cases this can progress to become a serious and potentially life threatening condition, called rhabdomyolysis.

Tell your doctor immediately if you experience any of the following effects:

- symptoms including tiredness, aching joints, pain in the abdomen, or yellowing of the skin and whites of the eyes (jaundice); these may be signs of hepatitis (inflammation of the liver)
- sudden persistent or severe pain in your abdomen or back; this may be a sign of pancreatitis (inflammation of the pancreas).

You may need urgent medical attention or hospitalisation if you experience any of the above side effects. These are very rare effects, affecting fewer than 1 person in 10,000.

The following side effects have been reported at the approximate frequencies shown:

Uncommon (affecting fewer than one person in 100 but more than one person in 1,000):

- skin reactions such as itching and rashes, or scalp and hair problems including hair loss
- muscle and joint pain
- dizziness, tiredness, headache and sleep disturbances
- problems with sight e.g. blurred or double vision
- bladder problems (painful or frequent urination, having to pass water at night)
- stomach and bowel problems such as indigestion, sickness, diarrhoea or constipation and wind
- sexual dysfunction.

Very rare (affecting fewer than one person in 10,000):

- problems with touch including burning/ tingling sensations or numbness, which may indicate damage to nerve endings
- pain or tenderness, muscle weakness, or muscle cramps
- temporary paralysis or swelling of muscles
- isolated cases of tendon disorders or rupture

- increase in certain enzyme levels in the body
- severe, rapid liver failure.

Side effects of unknown frequency:

- muscle weakness that is constant.
- liver failure
- Effects on skin and hair: rashes
- Muscle rupture

The treatment with pravastatin may be associated with depression, sleep disturbances (including insomnia and nightmare), memory loss and lung disease.

Treatment with pravastatin may also be associated with diabetes. This is more likely if you have high levels of sugars and fats in your blood, are overweight and have high blood pressure. Your doctor may monitor you while you are taking this medicine.

Treatment of Pravastatin may also be associated with dermatomyositis, a condition characterized by an inflammation of the muscles and the skin.

Myasthenia gravis (a disease causing general muscle weakness including in some cases muscles used when breathing).

Ocular myasthenia (a disease causing eye muscle weakness).

Talk to your doctor if you experience weakness in your arms or legs that worsens after periods of activity, double vision or drooping of your eyelids, difficulty swallowing, or shortness of breath.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRa Pharmacovigilance website: www.hpra.ie.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Pravastatin

Keep out of the sight and reach of children.

Do not use Pravastatin after the expiry date that is stated on the carton after 'EXP'. The expiry date refers to the last day of that month.

Do not store above 30°C. Store in the original package in order to protect from moisture.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What Pravastatin Tablets contain:

- The active ingredient is pravastatin sodium.
- Each tablet contains either 10, 20 or 40 mg of pravastatin sodium.
- The other ingredients are lactose, povidone (PVP K-30), crospovidone, calcium hydrogen phosphate (E341), sodium stearyl fumarate, cellulose microcrystalline (E460) and croscarmellose sodium (E466).
- The 10 mg tablets also contain red iron oxide (E172).
- The 20 mg tablets also contain yellow iron oxide (E172).

- The 40 mg tablets also contain quinoline yellow (E104) and brilliant blue FCF (E133).

What Pravastatin Tablets look like and contents of the pack:

- The 10 mg tablets are pink, mottled, round, shallow convex tablet with breakline on both sides.
- The 20 mg tablets are light yellow, round, shallow convex tablet with breakline on both sides.
- The 40 mg tablets are light green, round, shallow convex tablet with breakline on both sides.
- The tablets come in pack sizes of 28 tablets.

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