

PRAVASTATIN SODIUM

10 mg, 20 mg and 40 mg TABLETS

PACKAGE LEAFLET: INFORMATION FOR THE USER

Read all of this leaflet carefully before you start taking this medicine.

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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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 BEFORE YOU TAKE PRAVASTATIN

DO NOT take Pravastatin if you:

- are allergic (hypersensitive) to Pravastatin or any of the other ingredients of this medicine
- have current liver problems
- suffer from porphyria (a deficiency of specific enzymes within the body, causing an increase of substances called porphyrins)
- are pregnant or there is a possibility that you may become pregnant or are breast-feeding.

Take special care with Pravastatin

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

- have kidney problems
- are a child before puberty (puberty is the process of physical changes by which a child's body becomes an adult body capable of reproduction). In this case your doctor should properly evaluate the risk/benefit of treatment carefully before starting this medicine
- 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
- feel any unexplained cramps or muscle pains during treatment, tell your doctor immediately
- have problems with alcohol abuse (regularly drinking large amounts of alcohol)
- have severe respiratory failure.

While you are on this medicine your doctor will monitor you closely if you have diabetes or are 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.

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.

Taking other medicines

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, ciclosporin (an immunosuppressant used after an organ transplant), or nicotinic acid (vitamin B3), 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. colestyramine, colestipol (please see section 3, if you are also taking a bile acid sequestrant)
- the antibiotics erythromycin or clarithromycin. Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Taking Pravastatin with food and drink

- 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 blurred or double vision during treatment, if affected do not drive or operate machinery.

Important information about some of the ingredients of Pravastatin

- Patients who are intolerant to lactose should note that Pravastatin tablets contain a small amount of lactose. If your doctor has told you that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3 HOW TO TAKE PRAVASTATIN

Always take Pravastatin exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure. Your doctor will have explained 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)

- In the treatment of high levels of cholesterol and fats in the blood: the usual dose is 10-40 mg once a day, preferably in the evening.
- In the prevention of heart and blood vessel diseases: the usual dose is 40 mg once a day, preferably in the evening.

The maximum daily dose of 40 mg of pravastatin

should not be exceeded. Your doctor shall tell you which dose suits you.

• **Following organ transplantation**

Your doctor may prescribe a starting dose of 20 mg once a day. The dose may be adjusted up to 40 mg by your doctor.

If you are also taking a medicine which lowers the body's immune system (ciclosporin), your doctor may prescribe a starting dose of 20 mg once a day. The dose may be adjusted up to 40 mg by your doctor.

If you suffer from kidney or severe liver disease, your doctor may prescribe a lower dose of Pravastatin to you.

If you have the impression that the effect of this treatment is too strong or too weak, talk to your doctor or pharmacist.

Duration of treatment

Your doctor will indicate the duration of your treatment with Pravastatin. This medicine must be used very regularly and for as long as your doctor advises, even if it is for a very long time. Do not stop your treatment by yourself.

- **If you are also taking a bile acid sequestrant**, such as colestyramine 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.

Children (8-13 years) and adolescents (14-18 years) with a hereditary disease which increases the level of cholesterol in the blood:

The usual dose is 10 to 20 mg once a day between 8 and 13 years and from 10 to 40 mg once a day between 14 and 18 years.

If you take more Pravastatin than you should

If you (or someone else) swallow a lot of the tablets all together, 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 Pravastatin and tell your doctor immediately if 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, muscle problems can be serious (rhabdomyolysis) and can lead to a serious, life threatening kidney disease.

Sudden severe allergic reactions including swelling of the face, lip, tongue or wind pipe which can cause great difficulty in breathing. This is a very rare reaction which can be serious if it occurs. You should tell your doctor immediately if it happens.

The following side effects are uncommon and may affect more than 1 out of 1,000 persons:

- **Effects on nervous system:** insomnia, dizziness, tiredness, headache or sleep disturbances;
- **Effects on vision:** blurred or double vision;
- **Digestive effects:** indigestion, nausea, vomiting, stomach pain or discomfort, painful sensation in chest due to stomach acidity, diarrhoea or constipation and wind;
- **Effects on skin and hair:** itching, pimples, hives,

rashes, scalp and hair problems (including hair loss);

- **Urinary and genital effects:** bladder problems (painful or more frequent urination, having to pass water at night) and sexual difficulties;
- **Effects on muscles and joints:** muscle and joint pain.

The following side effects are very rare and may affect less than 1 out of 10,000 persons:

- **Effects on nervous system:** problems with touch including burning or tingling sensations or numbness which may indicate damage to nerves;
- **Effects on skin:** a severe skin disease (lupus erythematosus-like syndrome);
- **Effects on liver:** inflammation of the liver or pancreas; jaundice (recognisable by a yellowing of the skin and of whites of the eyes; very rapid death of liver cells (fulminant hepatic necrosis);
- **Effects on muscles and bones:** inflammation of one or more muscles leading to pain or weakness in muscles (myositis or polymyositis); pain or weakness in muscles, inflammation of tendons which may be complicated by rupture of tendons. Breakdown of muscle associated with acute kidney failure
- **Abnormal blood tests:** increases in transaminases (a group of enzymes occurring naturally in the blood) which may be a sign of liver problems. Your doctor may want to perform tests periodically to check these.

The following side effects have been reported with some Statins (Frequency unknown):

- Nightmare
- Memory loss
- Depression
- Breathing problem including persistent cough and or/shortness of breath or fever
- 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 will monitor you while you are taking this medicine.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5 HOW TO STORE PRAVASTATIN

Keep out of the reach and sight of children.

This medicinal product does not require any special storage conditions.

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

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6 FURTHER INFORMATION

What Pravastatin Tablets contain:

- The active ingredient is Pravastatin sodium.
- The other ingredients are crospovidone, lactose monohydrate and magnesium stearate.

What Pravastatin Tablets look like and contents of the pack:

- The 10 mg tablets are white to off white, round biconvex tablets, scored on one side of the tablet, debossed "P" and "10" on the other side.
- The 20 mg tablets are white to off white, round biconvex tablets, scored on one side of the tablet, debossed "P" and "20" on the other side.
- The 40 mg tablets are white to off white capsule-shaped tablets, scored on one side of the tablet, debossed "P" on the other side.
- The tablets come in pack sizes of 20, 28, 50, 100 and 200 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer
Marketing Authorisation holder and company responsible for manufacture: TEVA UK Limited, Eastbourne, BN22 9AG.

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