PACKAGE LEAFLET

Package leaflet: Information for the patient
Pravastatin Sodium 10 mg, 20 mg, 40 mg Tablets
pravastatin sodium

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 of the side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Pravastatin Sodium is and what it is used for
2. What you need to know before you take Pravastatin Sodium
3. How to take Pravastatin Sodium
4. Possible side effects
5. How to store Pravastatin Sodium
6. Contents of the pack and other information

1. What Pravastatin Sodium is and what it is used for

Pravastatin, the active substance of Pravastatin Sodium, belongs to a group of medicines called statins (or HMG-CoA reductase inhibitors). It prevents the production of cholesterol by the liver and consequently reduces the levels of cholesterol and other fats (triglycerides) in your body. When there are excessive levels of cholesterol in the blood, the cholesterol accumulates on the walls of blood vessels and blocks them.

This condition is called hardening of the arteries or atherosclerosis and it may lead to:
- chest pain (angina pectoris), when a blood vessel in the heart is partially blocked,
- a heart attack (myocardial infarction), when a blood vessel in the heart is completely blocked,
- a stroke (cerebrovascular accident), when a blood vessel in the brain is completely blocked.

Pravastatin Sodium is used in three situations:

<u>In the treatment of high levels of cholesterol and fats in the blood</u>
Pravastatin Sodium is used to lower high levels of ‘bad’ cholesterol and to raise the levels of ‘good’ cholesterol in the blood when changes to diet and exercise have failed to adequately do this.

<u>In the prevention of heart and blood vessel diseases</u>
- If you have high levels of cholesterol in your blood and risk factors favouring these diseases (if you smoke, are overweight, if you have high blood sugar levels or high blood pressure, if you do not exercise regularly), Pravastatin Sodium is used to reduce the risk of you having heart and blood vessel diseases and to lower your risk of dying from these diseases.
- If you have already had a stroke or if you have pains in the chest (unstable angina), and even if you have normal cholesterol levels, Pravastatin Sodium is used to reduce the risk of you having another heart attack or stroke in the future, and to lower your risk of dying from these diseases.

<u>After organ transplants</u>
If you have had an organ transplant and receive medication to prevent your body rejecting the transplant, Pravastatin Sodium is used to reduce increased levels of fats in the blood.

2. What you need to know before you take Pravastatin Sodium

Do not take Pravastatin Sodium:

- if you are allergic to pravastatin, or any of the other ingredients of this medicine (listed in section 6)
- if you suffer from liver disease or if liver function tests keep showing excessive values without any identifiable reason (your doctor will advise you about this)
- if you are pregnant, trying to become pregnant or if you are breast-feeding feeding (see Pregnancy and breast-feeding).

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Warnings and precautions:

Talk to your doctor or pharmacist before taking Pravastatin Sodium:

- if you 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 suffer from a kidney disease or have a history of liver disease
- if you regularly drink large amounts of alcohol
- if you suffer from a low function of your thyroid gland
- if you are taking other medications (e.g. fibrates) to lower fatty substances in your blood
- if you have experienced muscle problems during previous treatment to lower the fatty substances in your blood or if you or anyone in your family suffers from a hereditary muscle disease, especially if you are aged over 65 years of age.

Your doctor should do a blood test before you start taking Pravastatin Sodium and, if you have any symptoms of liver problems, while you take this medicine. 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 Sodium.

The risk of muscle breakdown is greater in certain patients. Tell your doctor if any of the following applies to you:

- if you 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 Sodium can lead to serious muscle problems (rhabdomyolysis)
- if you have severe respiratory failure.

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 muscle-related side effects. You may also need this blood test if you are 70 years or older.

Consult your doctor immediately if, while using Pravastatin Sodium, you get unexplained muscle ache, muscle weakness, muscle cramps or tenderness, particularly in combination with tiredness, fever and red-brown discolouration of urine (rhabdomyolysis), which can be a sign of kidney problems. These symptoms may be caused by the use of Pravastatin Sodium.

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 or fats in your blood, are overweight or have high blood pressure.

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 are at risk of developing diabetes. You are likely to be at risk of developing diabetes if you have high levels of sugars or fats in your blood, are overweight or have high blood pressure.

Children
This medicine is not recommended for children younger than 8 years old.

Other medicines and Pravastatin Sodium
Tell your doctor or pharmacist if you are taking have recently taken or might take any other medicines, including medicines obtained without a prescription.

If you take Pravastatin Sodium together with certain other medicines, the effect either of Pravastatin Sodium or of the other medicine or of both may be influenced and can increase the risk of muscle problems.

Tell your doctor or pharmacist especially if you are taking or have recently taken any of the following medicines:

- medicines known as fibrates (eg. Gemfibrozil and fenofibrate) which decrease fat levels in the blood or nicotinic acid (a B vitamin). Taking these medicines with pravastatin may cause severe muscle disorders
- medicines such as colestyramine and colestipol used for the treatment of a high cholesterol level because they may reduce the effectiveness of pravastatin. Pravastatin sodium should be taken at least one hour before or four hours after you have taken these medicines
- ciclosporin (a medicine used to suppress the immune system) because the effect of pravastatin may be increased and your doctor may need to change your dose
- antibiotics such as erythromycin, clarithromycin roxithromycin and rifampicin because these increase the effect of pravastatin
- 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 Sodium. Taking Pravastatin Sodium with fusidic acid may rarely lead to muscle weakness, tenderness or pain (rhabdomyolysis). See more information regarding rhabdomyolysis in section 4.
- 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 Sodium because the use of vitamin K antagonists concomitantly with Pravastatin Sodium might increase the results of blood tests used to monitor the treatment with vitamin K antagonists.
- colchicine (used to treat gout).
- lenalidomide (used to treat a type of blood cancer called multiple myeloma).

Pravastatin Sodium with food, drink and alcohol
This treatment can be taken with or without food, with half a glass of water.
You should always keep your alcohol intake to a minimum. If you are concerned about how much alcohol you can drink while you are taking this medicine, you should discuss this with your doctor.

Pregnancy and breast-feeding
Do not take Pravastatin Sodium during pregnancy or whilst breast-feeding as pravastatin may harm your baby.

Before you start using Pravastatin Sodium, you should inform your doctor if you are pregnant or intend to become pregnant. If you become pregnant during treatment, you should stop using Pravastatin Sodium and consult your doctor.

Women of childbearing age should use a reliable contraceptive whilst taking this medicine.
Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines
Pravastatin Sodium does not usually affect the ability to drive and use machines. You may, however, feel a bit dizzy or your vision may be affected. Avoid driving or operating machines if you feel unwell after taking pravastatin.

Pravastatin Sodium contains lactose and sodium
If you have an intolerance to some sugars, contact your doctor before taking this medicine. This medicine also contains less than 1 mmol sodium (23 mg) per dosage unit, that is to say essentially 'sodium-free'.

3. How to take Pravastatin Sodium

Your doctor will advise you on a low-fat diet which you should continue over the full treatment period.

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

For lowering an increased cholesterol level in the blood
The recommended dose is 10-40 mg pravastatin taken once per day, preferably in the evening. The maximum daily dose is 40 mg pravastatin.

To prevent heart and vessel disease
The recommended dose is 40 mg pravastatin taken once per day, preferably in the evening.

Following a transplant
The recommended dose is 20 mg pravastatin taken once per day. The dosage can be adjusted up to 40 mg pravastatin. Your doctor will tell you how much to take.

Use in children and adolescents with hereditary increased cholesterol in the blood (heterozygous familial hypercholesterolaemia)
The recommended dose is 10-20 mg pravastatin taken once per day for children 8-13 years of age and 10-40 mg pravastatin taken once per day in adolescents 14-18 years of age.

Elderly
No dosage adjustment is required for this group. The same dosage as for adult patients can be used. Your doctor will tell you how much to take.

Dosage adjustment in kidney or liver disorder
The typical dose is 10 mg pravastatin taken once per day but may be higher. Your doctor will tell you how much to take.

Use with other medicines
If you take Pravastatin and other medicines containing colestyramine or colestipol (medicines also used for the treatment of high cholesterol levels), you should take Pravastatin Sodium at least one hour before or four hours after these medicines.

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. Your doctor will tell you how much to take.

Take Pravastatin Sodium once daily, preferably in the evening, with or without food. Swallow the tablets with a sufficient quantity of liquid (e.g. one glass of water).

20 mg and 40 mg Tablets: The tablet can be divided into equal doses

Your doctor will tell you how long you have to take Pravastatin Sodium. This depends on why you are taking this medicine.

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

If you take more Pravastatin Sodium than you should
If you have taken too many tablets, or if someone has accidentally taken your tablets, contact your doctor or pharmacist immediately.

If you forget to take Pravastatin Sodium
If you miss a dose do not worry. Simply take your normal dose when it is next due. Do not take a double dose to make up for a forgotten dose.

If you stop taking Pravastatin Sodium
Take Pravastatin Sodium as long as your doctor has told you. If you stop taking Pravastatin Sodium, your cholesterol levels may increase again.

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

4. Possible side effects

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

Contact your doctor immediately if you develop one of these side effects during the use of Pravastatin Sodium:

Very rare (may affect up to 1 in 10,000 people):
- hypersensitivity reactions:
  - serious allergic reaction causing swelling of the face, lips, throat, tongue and excessive fluid in your body which can produce difficulty in swallowing or breathing (angioedema, anaphylaxis)
  - skin rash, possibly with pain in the joints (Lupus erythematous-like syndrome)
- destruction of muscle fibres (rhabdomyolysis) that may be associated with acute kidney failure (see also section 2. "What you need to know before you take Pravastatin Sodium"), inflammation of the muscles/many muscles (myositis/polymyositis). This may cause aching muscles, muscle tenderness or weakness not caused by exercise, muscle strains, tears and rupture, decreased urine, dark coloured urine and increased creatinine kinase which can be seen in a blood test. Presence of myoglobin in the urine which can be seen in a urine test (myoglobinuria)
- serious liver problems including yellowish discoloration of the skin and/or eyes (jaundice), tissues and body fluids, liver inflammation (hepatitis) sudden rapid destruction of liver tissue (fulminant hepatic necrosis). This may cause you to feel or be sick, lose appetite, feel generally unwell, fever, itchy skin, dark urine, pale stools
- inflammation of the pancreas. This causes moderate to severe pain in the stomach, which spreads to the back (pancreatitis)
- problems with touch including burning/tingling sensation, numbness or pins and needles (paresthesia) may occur which may be a sign of damage to the nerve endings (peripheral polyneuropathy)
- a condition characterised by an inflammation of the muscles and the skin (dermatomyositis).

Not known (cannot be estimated from the available data):

- diabetes. This is more likely if you have high levels of sugars or fats in your blood, are overweight or have high blood pressure. Your doctor will monitor you while you are taking this medicine
- breathing problems including persistent cough with shortness of breath and/or fever (interstitial lung disease)
- muscle weakness that is constant (Immune – mediated necrotising myopathy).
- myasthenia gravis (a disease causing general muscle weakness including in some cases muscles used when breathing).
- ocular myasthenia (a disease causing eye muscle weakness).
- muscle strains, tears and rupture.

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.

Other possible side effects include:

Common (may affect up to 1 in 10 people):
- painful joints (arthralgia)
- increased production of liver enzymes which can be seen in a blood test.

Uncommon (may affect up to 1 in 100 people):
- dizziness, headache, sleep disturbances, difficulty sleeping
- problems with eyesight, blurred vision or double vision
- digestive problems or slow digestion, indigestion/heartburn, abdominal pain, feeling/being sick, difficulty or delay emptying bowels, diarrhoea, wind
- itching, rash, hives, scalp and hair problems (inclusive of hair loss)
- abnormal urination, e.g. pain, frequency, frequent urination at night
- problems with sexual functions
- tiredness
- inflamed tendons, sometimes associated with tearing.

- **Rare (may affect up to 1 in 1,000 people**: increased sensitivity to light (photosensitivity).

The following side effects have been seen with other medicines similar to pravastatin, and may be seen with this medicine.

Not known (cannot be estimated from the available data):
- nightmares
- memory loss
- depression.

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 the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Pravastatin Sodium

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and blister after "EXP". The expiry date refers to the last day of that month.

Store in the original packaging 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 protect the environment.

6. Contents of the pack and other information

What Pravastatin Sodium contains:

- the active substance is pravastatin sodium
  pravastatin Sodium 10 mg tablets: each tablet contains 10 mg of pravastatin sodium
  pravastatin Sodium 20 mg tablets: each tablet contains 20 mg of pravastatin sodium
  pravastatin Sodium 40 mg tablets: each tablet contains 40 mg of pravastatin sodium

- the other ingredients are lactose, monohydrate (see section 2 'Pravastatin Sodium contains lactose'), dihydroxy aluminium sodium carbonate, sodium stearyl fumarate, ironoxide red (E172) (for the 10 mg and 40 mg tablets only) and iron oxide yellow (E172) (for the 20 mg tablet only).

What Pravastatin Sodium looks like and contents of the pack
10 mg Tablets:
Light pink colour, mottled, round, flat, bevelled tablets debossed with '10' on one side and plain on the other.

20 mg Tablets:
Light yellow colour, mottled, round tablet debossed with '20' on one side and break line on the other side. The tablet can be divided into equal halves.

40 mg Tablets:
Light pink colour, mottled, round tablet debossed with '40' on one side and break line on the other side. The tablet can be divided into equal halves.

Pravastatin Sodium is available in blister packs with 10, 14, 20, 28, 30, 50, 60, 84, 90, 98 or 100 tablets.

Not all pack sizes may be marketed.

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