

PACKAGE LEAFLET: INFORMATION FOR THE USER

Pravastatin sodium 10mg, 20mg and 40mg Tablets

(pravastatin sodium)

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 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.

In this leaflet:

1. What Pravastatin sodium Tablets are and what they are used for
2. Before you take Pravastatin sodium Tablets
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1. WHAT PRAVASTATIN SODIUM TABLETS ARE AND WHAT THEY ARE USED FOR

The active substance in your medicine is called pravastatin sodium which belongs to a group of medicines known as statins or "HMG-CoA reductase inhibitors". These work by reducing the amount of cholesterol and other fatty substances called triglycerides in your blood.

Cholesterol is important for the body to work properly but if cholesterol levels are too high (hypercholesterolaemia), it can build up on the walls of the arteries which can lead to a blockage of the blood vessels. This can lead to angina (crushing chest pain) and a heart attack.

High cholesterol in your blood may be caused by many factors, including a diet high in cholesterol and fats, certain existing diseases, inherited disease and lack of exercise.

Your doctor may have prescribed Pravastatin sodium Tablets as an addition to dietary measures for one of the following reasons:

- You have high levels of cholesterol or fatty substances in your blood, which have not been lowered by diet, weight loss or exercise, or
- You are suffering from coronary heart disease (CHD) or you are at risk of developing CHD because you have diabetes, have had a stroke, or other blood vessel disease or suffered from chest pain (unstable angina pectoris). Pravastatin sodium may prolong your life by reducing the risk of heart disease by helping to keep your arteries clear, even if your cholesterol levels are normal, or
- You have high cholesterol levels and you are taking medicines to stop your body rejecting a recent organ transplant.

Your doctor will also advise you of how to reduce the levels of cholesterol in your blood by eating a low fat diet throughout your treatment with Pravastatin sodium Tablets.

2. BEFORE YOU TAKE PRAVASTATIN SODIUM TABLETS**Do not take Pravastatin sodium Tablets**

- If you are allergic (hypersensitive) to pravastatin sodium or any of the other ingredients of Pravastatin sodium Tablets (see section 6 Further Information)
- If you are pregnant or planning to become pregnant.
- If you are breast-feeding
- If you have liver problems.

Take special care with Pravastatin sodium Tablets

Pravastatin sodium Tablets may increase the risk of myopathy in some patients, which results in muscle pain, tenderness and weakness. The doctor may perform a blood test to check the condition of your muscles before and after starting treatment with Pravastatin sodium Tablets.

Talk to your doctor BEFORE taking the tablets if any of the following apply to you as you may have a greater risk of myopathy:

- **if you experience unexplained muscle pain, tenderness or weakness, or if you have ever suffered from an illness called myopathy (muscle disease)**
- if you have ever had muscle problems during treatment with cholesterol lowering medicines called 'statins' (such as simvastatin or atorvastatin) or "fibrates" (such as gemfibrozil and fenofibrate)

- if you drink substantial amounts of alcohol or if you have a past history of liver disease. Your doctor may conduct some blood tests to check your liver before and after starting treatment
- if you or close family members have a hereditary muscle disorder
- if you have any kidney or thyroid problems
- if you are more than 70 years old
- if you have a past history of liver disease.

Check with your doctor or pharmacist before taking Pravastatin sodium Tablets if you:

- 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.

Taking other medicines

The risk of muscle problems can be greater if Pravastatin sodium Tablets are taken with other medicines. You should tell your doctor if you are taking any of the following medicines as these may increase your risk:

- Medicines called fibrates e.g. gemfibrozil or fenofibrate, (used to lower cholesterol).

Other medicines may be affected by Pravastatin sodium Tablets.

They, in turn, may affect the way pravastatin sodium works. Please tell your doctor if you are taking any of the following medicines:

- Medicines used to suppress the immune system such as ciclosporin
- Niacin or nicotinic acid in doses greater than or equal to 1g per day (these are medicines used to lower cholesterol)
- Medicines containing colestyramine or colestipol (often used to lower your cholesterol)
- Antibiotics such as erythromycin or clarithromycin.

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

Taking Pravastatin sodium Tablets with food and drink

Pravastatin sodium Tablets can be taken with or without food.

Pregnancy and breast-feeding

Do not take Pravastatin sodium Tablets if you are pregnant, trying to become pregnant or think you may be pregnant. If you become pregnant while taking Pravastatin sodium Tablets, stop taking it immediately and contact your doctor.

Do not take Pravastatin sodium Tablets if you are breast-feeding.

Speak to your doctor before taking the tablets if you are planning to breast-feed or if you are already breast-feeding.

Driving and using machines

This medicine can make you feel dizzy. If this happens, you should not drive or operate machinery until you feel better.

Important information about some of the ingredients of Pravastatin sodium Tablets:

This product contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking Pravastatin sodium Tablets.

3. HOW TO TAKE PRAVASTATIN SODIUM TABLETS

Always take Pravastatin sodium Tablets exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Pravastatin sodium Tablets should be taken as a single dose in the evening or at night. Swallow the tablets whole with a glass of water. The usual dose is:

Adults (18 years and over):

The usual starting dose for lowering cholesterol is 10mg once a day. This dose may be increased by your doctor to 40mg once a day.

The starting and maintenance dose for prevention of coronary heart disease is 40mg.

The dose following organ transplantation may be increased by the doctor to 40mg.

The starting dose for patients with moderate or severe renal or significant hepatic problems is 10 mg a day. The dosage may be adjusted by your doctor based on your response.

Children and adolescents aged 8-13 years:

The usual starting dose for lowering cholesterol is 10mg once a day. This dose may be increased by your doctor to 20mg once a day.

Adolescents aged 14-18 years:

The usual starting dose for lowering cholesterol is 10mg once a day. This dose may be increased by your doctor to 40mg once a day.

If you are taking a medicine containing cholestyramine or colestipol (to lower your cholesterol), Pravastatin sodium Tablets should usually be taken at least one hour before or four hours after you have taken these medicines. This is because these medicines can affect the absorption of pravastatin if they are taken too closely together.

If you take more Pravastatin sodium Tablets than you should, or if someone accidentally swallows some tablets, contact your doctor or pharmacist as soon as possible or go to your nearest hospital casualty department immediately. Remember to take the pack and any remaining tablets with you.

If you forget to take Pravastatin sodium Tablet(s), do not worry. Simply take your next dose when it is next due. Do not take a double dose to make up for a forgotten dose.

If you stop taking your Pravastatin sodium Tablets, your cholesterol level may rise again. Keep taking your tablets for as long as your doctor has asked you to.

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, Pravastatin sodium Tablets can have side effects, although not everybody gets them.

Very rarely, patients have developed muscle wasting or inflammation and this has progressed to become a serious, potentially life-threatening condition (called rhabdomyolysis). If you have muscle aches, weakness, tenderness or pain and particularly at the same time you feel unwell or have a high temperature, stop taking the tablets and tell your doctor immediately.

All medicines can cause allergic reactions, although serious allergic reactions are very rare. Tell your doctor straight away if you get any sudden wheeziness, difficulty in breathing, swelling of the eyelids, face or lips, rash or itching (especially affecting your whole body), joint pains, joint and blood vessel inflammation, unusual bruising, skin eruptions, swelling, hives, skin sensitivity to the sun, a high temperature, or flushing.

Other possible side effects reported with some statins are:

- Sleep disturbances, including insomnia and nightmares
- Memory loss
- Sexual difficulties
- Depression
- Breathing problems 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.

The following side effects have been reported with pravastatin:

Uncommon side effects (less than 1 in 100 but greater than 1 in 1000 people);

- dizziness
- headache
- sleeping problems
- sleep disturbances (insomnia)
- vision disturbance such as blurred or double vision
- stomach upsets (such as feeling or being sick, constipation, diarrhoea, flatulence (wind), indigestion and stomach pains),
- hair loss
- rash
- itchiness
- impotence
- tiredness
- feeling of weakness
- changes in the way your liver works
- heartburn
- bladder problems (painful or frequent urination).

Very rare side effects (less than 1 in 10,000 people including isolated reports);

- numbness or loss of sensation in the arms and legs
- tingling or pins and needles (paresthesia)
- inflammation of the liver or pancreas
- severe allergic reactions including localised swelling of the face, lips and / or throat
- yellowing of the skin and whites of eyes (jaundice)
- muscle and joint pain.

If any of these 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 SODIUM TABLETS

Keep out of the sight and reach of children.

Pravastatin sodium Tablets should be stored below 25°C. Keep the container tightly closed. Store them in the original package.

Do not use Pravastatin sodium Tablets after the expiry date which is stated on the carton and on each blister strip of tablets. 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 sodium Tablets contain:

The active substance is pravastatin sodium. Each tablet contains 10mg, 20mg or 40mg of pravastatin sodium.

The other ingredients in the tablet are lactose monohydrate, microcrystalline cellulose, magnesium aluminium silicate, croscarmellose sodium, povidone, talc, and magnesium stearate.

What Pravastatin sodium Tablets look like and contents of the pack:

Pravastatin sodium 10mg Tablets are white to off white capsule shaped tablet marked > on one side of the tablet and "PV|10" on the other side.

Pravastatin sodium 20mg Tablets are white to off-white, capsule shaped tablet marked > on one side of the tablet and "PV scoreline 20" on the other side.

Pravastatin sodium 40mg Tablets are white to off-white, capsule shaped tablet marked > on one side of the tablet and "PV 40" on the other side.

Pravastatin sodium 10 and 20mg Tablets are available in blister packs of 10, 20, 28, 30, 50, 56, 60, 98, 100 and 500 (5x100) tablets and containers of 30, 250, and 1000 Tablets.

Pravastatin sodium 40mg Tablets are available in blister packs of 10, 14, 20, 28, 30, 50, 56, 60, 98, 100 and 500 (5x100) tablets and containers of 30, 250 and 750 Tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder:

Arrow Generics Limited, Unit 2, Eastman Way, Stevenage, Hertfordshire, SG1 4SZ, United Kingdom.

Manufacturer:

Arrow Pharm (Malta) Ltd, HF 62, Hal Far Industrial Estate, Birzebbugia BBG 06, Malta.

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