Package leaflet: Information for the patient

Pravitin 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 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 Pravitin is and what it is used for

Pravitin belongs to a group of medicines called HMG-CoA reductase inhibitors (or statins) which work by reducing your body's production of "bad cholesterol" and raising the levels of "good" cholesterol. Cholesterol is a lipid that can cause coronary heart disease by narrowing the vessels that supply the heart with blood. This condition, called hardening of the arteries or atherosclerosis, may lead to chest pain (angina pectoris), a heart attack (myocardial infarction) or stroke.

This medicine is used in 3 situations:

In the treatment of high levels of cholesterol and fats in the blood
Pravitin 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.

In the prevention of heart and blood vessel diseases
- 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 take little exercise), Pravitin 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 heart attack or if you have pains in the chest (unstable angina pectoris), and even if you have normal cholesterol levels, Pravitin 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.

After organ transplants
If you have had an organ transplant and receive medicine to prevent your body rejecting the transplant, Pravitin is used to reduce increased levels of fats in the blood.

2 What you need to know before you take Pravitin

Do not take Pravitin:
- if you are allergic to pravastatin sodium or any of the other ingredients of this medicine (listed in section 6)
- if you are pregnant, trying to become pregnant or if you are breast-feeding (see section "Pregnancy and breast-feeding")
- if you have an active liver disease (see section 2: Warnings and precautions)
- if several blood tests have shown abnormal functioning of your liver (increased levels of liver enzymes in the blood).

Ask your doctor if you are uncertain whether you can take Pravitin.

Warnings and precautions
Talk to your doctor or pharmacist before taking Pravitin if you have or have had any of the following medical problems:

- kidney disease
- an underactive thyroid (hypothyroidism)
- a liver disease
- alcohol problems (regularly drinking large amounts of alcohol)
- muscle disorders caused by a hereditary disease (affecting you or your relative)
- muscle problems caused by another cholesterol-lowering medicine such as a statin or fibrate (see Other medicines and Pravitin)
- if you have severe respiratory failure
- 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 Pravitin can lead to serious muscle problems (rhabdomyolysis).

If you have suffered from any of these problems, your doctor will need to carry out a blood test before and possibly during Pravitin treatment to assess your risk of muscle-related side effects. You may also need this blood test if you are aged older than 70 years.
Go back to your doctor as soon as possible to discuss your concerns and follow the advice given.

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.

Your doctor should do a blood test before you start taking Pravitin and if you have any symptoms of liver problems while you take Pravitin. 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 Pravitin.

If you suffer from unexplained muscle pain, tenderness, weakness or muscle cramps and are taking statins, contact your doctor without delay.

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.

Check with your doctor or pharmacist before taking Pravitin if you:
- have severe respiratory failure.

Children and adolescents
Children and adolescents (8 – 18 years of age) with a hereditary disease which increases the level of cholesterol in the blood (heterozygous familial hypercholesterolaemia): In children before puberty, the benefit and risk of treatment should be carefully evaluated by the doctor before starting the treatment.

Other medicines and Pravitin
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

It is important that you inform your doctor if you are already being treated with any of the following medicines because the combination may increase the risk of muscle problems:
- other cholesterol lowering medicines called **fibrates** (e.g. gemfibrozil, fenofibrate) and **nicotinic acid**.
- medicines used to adjust or adapt the immune response, e.g. **ciclosporin**.
- the antibiotics **erythromycin**, **clarithromycin and roxithromycin.**
- rifampicin (an antibiotic used to treat an infection called tuberculosis).
- colchicine (used to treat gout attacks).
- lenalidomide (used to treat a type of blood cancer called multiple myeloma).

A resin-type lipid-lowering medicine such as **colestyramine** or **colestipol.** Pravitin should usually be taken at least one hour before or four hours after you have taken the resin. This is because the resin can affect the absorption of Pravitin if the two medicines are taken too closely together).

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

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 Pravitin. Taking Pravitin with fusidic acid may rarely lead to muscle weakness, tenderness or pain (rhabdomyolysis). See more information regarding rhabdomyolysis in section 4.

Pravitin with food, drink and alcohol
Inform your doctor if you regularly consume larger quantities of alcohol.
If you are not sure about this please follow your doctor's guidelines.

Pregnancy and breast-feeding
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Pregnancy:
You must not take Pravitin during pregnancy. Doctors will take special care when prescribing this medicine to young women that might become pregnant and they will properly explain the potential risk associated with pravastatin therapy during pregnancy. If you have plans to become pregnant or if you have become pregnant, you must stop taking Pravitin and inform your doctor immediately (see Section 2: Do not take Pravitin).

Breast-feeding
You must not take Pravitin during breast-feeding, as Pravitin passes into the mother's milk (see Section 2: Do not take Pravitin).

Driving and using machines
Pravitin does not usually affect your ability to drive or use machines. If you experience any dizziness, blurred or double vision during treatment make sure you are fit to drive and use machines before attempting to do so.

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

3 How to take Pravitin

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

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

Pravitin is taken once daily, preferably in the evening, with or without food, with half a glass of water.

The tablet can be divided into equal doses.

Adults

In the treatment of high levels of cholesterol and fats in the blood
The recommended dose is 10 – 40 mg once daily.

In the prevention of heart and blood vessel diseases
The recommended dose is 40 mg once daily.

Dosage after organ transplantation
Your doctor may prescribe a starting dose of 20 mg once daily. The dose may be adjusted up to 40 mg by your doctor.

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The maximum daily dose of 40 mg of pravastatin should not be exceeded. Your doctor shall tell you which dose suits you.

Use in children and adolescents (8 – 18 years of age) with a hereditary disease which increases the level of cholesterol in the blood (heterozygous familial hypercholesterolemia)

Use in children and adolescents (8 – 13 years of age):
The recommended dose is 10 - 20 mg once daily.

Use in children and adolescents (14 – 18 years of age):
The recommended dose is 10 - 40 mg once daily (for adolescent females of child-bearing potential see section "Pregnancy").

Patients with kidney or liver disease
The usual dose is 10 mg once daily in patients with moderate or severe kidney disease or severe liver disease.

Taking other medicines
This medicine should usually be taken at least one hour before or four hours after you have taken the **Colestyramine** or **Colestipol**.

If you are also taking medicine which adjust or adapt the immune response (**Ciclosporin**), your doctor may prescribe a starting dose of 20 mg once daily. The dose may be adjusted up to 40 mg by your doctor.

Duration of treatment
Your doctor will indicate the duration of your treatment with this medicine. 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 have the impression that the effect of Pravitin is too strong or too weak, talk to your doctor or pharmacist.

If you take more Pravitin than you should
If you have taken too many tablets, or if someone accidentally swallows some, contact your doctor or the nearest hospital for advice.

If you forget to take Pravitin
If you miss a dose, simply take your usual dose when it is next due. Do not take a double dose to make up for forgotten dose.

If you stop taking Pravitin
Always tell your doctor if you want to stop the treatment.

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.

Serious side effects which occur very rarely (may affect up to 1 in 10,000 people)

Contact your doctor as soon as possible and stop taking Pravitin if you develop any unexplained or persistent muscle and joint 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 and potentially life-threatening kidney disease.

You should stop taking Pravitin and contact your doctor immediately if you notice any of the following side effects:
- swelling of the face, lips, mouth, tongue, eyes or throat
- difficulty to swallow
- rash, hives (urticaria)
- difficulty in breathing
- dizziness.

These are symptoms of **serious allergic reactions** (angioedema, anaphylaxis) which must be treated immediately, usually in a hospital.

Other side-effects

Uncommon side effects (may affect up to 1 in 100 people):
- sleep disturbances, difficulty in sleeping
- dizziness, headache, tiredness
- problems with sight such as blurred or double vision
- stomach and bowel problems such as indigestion, heartburn, nausea, vomiting, stomach pain or discomfort, diarrhoea or constipation and wind
- skin reactions such as itching and rashes, hives (urticaria) or scalp and hair problems including hair loss
- bladder problems (painful or more frequent urination, having to pass water at night)
- sexual difficulties
- muscle and joint pain
- inflammation of tendons, which may be complicated by rupture of tendons.

Rare side effects (may affect up to 1 in 1,000 people):
- increased sensitivity of skin to sunlight.

Very rare side effects (may affect up to 1 in 10,000 people):
- problems with touch including burning/tingling sensations or numbness which may indicate damage to nerve endings
- allergic condition which causes joint pain, skin rashes and fever (*lupus erythematosus*), acute and severe hypersensitivity reaction (anaphylaxis)
- liver problems which may cause yellowing of the skin or the whites of the eyes and/or poor appetite and generally feeling unwell (jaundice, inflammation of the liver), rapidly occurring loss of liver function, inflammation of pancreas (which may cause stomach pain)
- pain or weakness in muscle (myopathy), inflammation of the muscles (myositis, polymyositis)
- 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.
- inflammation of the skin and muscles (dermatomyositis).

Side effects of unknown frequency (frequency cannot be estimated from the available data):
- muscle weakness that is constant
- very serious loss of liver function, which may end with death
- rash including – lichenoid rash
- very serious pain or weakness in muscle, which is caused by disturbances in immune system (Immune-mediated necrotising myopathy).

The following side effects have been reported with some statins (medicines of the same type):
- nightmares
- memory loss
- 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.

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, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5 How to store Pravitin

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 outer carton and blister or container after 'EXP'. The expiry date refers to the last day of that month.

Blister (Al/OPA/Al/PVC):
Do not store above 30°C.
Store in the original package in order to protect from light and moisture.

Blister (Al/PVC/COC/PVdC):
Do not store above 25°C.
Store in the original package in order to protect from light and moisture.

Tablet container:
Do not store above 30°C.
Keep the tablet container tightly closed in order to protect from light and 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 Pravitin contains
The active substance is pravastatin sodium.

Each tablet contains 40 mg pravastatin sodium.

The other ingredients are calcium hydrogen phosphate, anhydrous, sodium starch glycolate (Type A), cellulose - microcrystalline, trometamol, disodium phosphate dihydrate, povidone K30, magnesium stearate, iron oxide, yellow (E172).

What Pravitin looks like and contents of the pack
A yellow, oblong, biconvex, side wall scored tablet encoded P 40.

Blister (Al/PVC/COC/PVdC)
Blister (Al/OPA/Al/PVC)
Pack sizes: 7, 10, 14, 20, 28, 30, 50, 56, 60, 98, 100x1 and 100 tablets.

Polyethylene tablet container and polypropylene cap with desiccant (silica gel) insert.
Pack sizes: 28, 30, 98, 100 and 250 tablets.

Not all pack sizes or pack types may be marketed.

Marketing Authorisation Holder and Manufacturers
Marketing Authorisation Holder
Rowex Ltd., Bantry, Co. Cork, Ireland.

Manufacturers
Salutas Pharma GmbH, Otto-von-Guericke Allee 1, 39179 Barleben, Germany.
Rowa Pharmaceuticals Ltd., Bantry, Co. Cork, Ireland.
Lek Pharmaceuticals d.d., Verovškova 57, Ljubljana 1526, Slovenia.

This medicinal product is authorised in the Member States of the EEA under the following names:
IE Pravitin 40 mg Tablets
UK Pravastatin 40 mg tablet

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