Package leaflet: Information for the patient

Pravat 10 mg tablets
Pravat 20 mg tablets
Pravat 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 Pravat is and what it is used for

Pravat contains pravastatin sodium as the active ingredient. Pravastatin belongs to a group of medicines called HMG-CoA reductase inhibitors also known as statins, which work by lowering your body's production of cholesterol.

- If you already have heart disease, pravastatin reduces the risk of you having another heart attack or stroke, reduces the need for heart surgery and slows down any further narrowing of your arteries.

- If you do not have heart disease but have high cholesterol levels, pravastatin reduces the risk of you having a heart attack or needing heart surgery. Pravastatin should always be used together with a low fat diet.

- If you have had an organ transplant and are taking medication to stop your body rejecting the transplant, pravastatin reduces increased lipid levels.

2. What you need to know before you take Pravat

Do not take Pravat if:
- you are allergic to pravastatin sodium or any of the other ingredients of this medicine (listed in section 6)
- you are breast-feeding
- you are pregnant or there is a possibility that you may become pregnant
- you have or have had liver problems.

Warnings and precautions
Talk to your doctor or pharmacist before taking Pravat if:
- you have kidney problems
- you have thyroid problems
- you have had muscle problems with a statin or fibrate before
- you have a personal or family history of hereditary muscle problems
- you drink a lot of alcohol or have a history of alcohol abuse.
- 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 Pravastatin sodium tablets can lead to serious muscle problems (rhabdomyolysis).

Tell your doctor or pharmacist if any of the above applies to you. 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 more than 70 years of age.

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 body, are overweight and 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.

Children
Pravastatin is only recommended for use in children when they have an inherited condition called heterozygous familial hypercholesterolaemia (resulting in high levels of cholesterol in the blood).

Other medicines and Pravat
Tell your doctor or pharmacist if you are taking have recently taken or might take any other medicines.
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 tablets. Taking Pravastatin sodium tablets 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 "vitamine 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.

In particular, tell your doctor if you are currently taking any of the following medicines:
- Fibrates, example of drugs in this category include bezafibrate, ciprofibrate, fenofibrate and gemfibrozil
- Ciclosporin, an immunosuppressant
- The antibiotics erythromycin or clarithromycin
- Resin-type lipid-lowering agent such as colestyramine or colestipol. Pravastatin should 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 pravastatin if the two medicines are taken too closely together.

Pregnancy and breast-feeding
You must not use Pravat during pregnancy and/or breastfeeding.
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.

Driving and using machines
Pravat will not affect your ability to drive or operate machinery. However, if you experience side effects such as dizziness, blurred or double vision, your ability to drive or operate machinery may be affected.

Pravat contains lactose monohydrate
If you have been told that you do not tolerate certain kinds of sugar, contact your doctor before taking this medicine.

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

3. How to take Pravat

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

Swallow your tablets whole with half a glass of water. It does not matter whether you take your tablets before or after meals. However, pravastatin is best taken at bedtime because your body produces the most cholesterol when you are asleep and pravastatin acts best when it is taken at night.

Adults and adolescents (14 - 18 years): The recommended dose is 10 – 40 mg taken once a day, at bedtime.

Children (8-13 years): with heterozygous familial hypercholesterolaemia. The recommended dose is 10 – 20 mg once daily.

Your doctor may carry out a blood test after 4 weeks to check that your cholesterol has reduced.

If you take more Pravat than you should
If you accidentally take too many tablets, tell your doctor immediately, or go to your nearest emergency department. Remember to take this leaflet or the remaining tablets with you when you go to the hospital.

If you forget to take Pravat
If you forget to take your tablet, do not worry. Take your normal dose when it is next due. Do not take a double dose to make up for the one you missed.

If you stop taking Pravat
It is important that you continue to take your tablets until your doctor tells you otherwise. Your doctor will tell you to come back for regular check-ups. Keep your doctor's appointment even if you feel well.

4. Possible side effects

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

Please inform your doctor immediately:

- If you notice a severe allergic reaction including localised swelling of the face, lips and/or tongue, severe skin rashes.
- If you experience unexplained muscle pain, tenderness, weakness or cramps combined with dark, red, or cola coloured urine (rhabdomyolysis).

These side effects occur very rarely.

Uncommon (may affect up to 1 in 100 people)

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

Very Rare (may affect up to 1 in 10,000 people)

- problems with touch including burning/tingling sensations or numbness
- liver disorders such as jaundice (yellowing of skin and/or eyes) and inflammation (swelling) of the liver or pancreas
- muscle and joint pain.

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

- 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.

- Muscle weakness that is constant.

Overall list of possible side effects:
-Diabetes mellitus: Frequency will depend on the presence or absence of risk factors (fasting blood glucose at 5.6 mmol/L, BMI>30kg/m 2, raised triglycerides, history of hypertension).
-Dermatomyositis (condition characterized by an inflammation of the muscles and the skin).

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:

IMB Pharmacovigilance
Earlsfort Terrace
IRL - Dublin 2
Tel: +353 1 6764971
Fax: +353 1 6762517
Website: www.imb.ie
e-mail: imbpharmacovigilance@imb.ie

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

5. How to store Pravat

- Keep this medicine out of the sight and reach of children
- Store below 25 ºC
- Store the tablets in the original package. Only remove them when it is time to take your medicine.

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.

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 Pravat contains
Pravat is available in three different strengths: 10 mg, 20 mg and 40 mg.
The active substance is pravastatin sodium. The other ingredients are lactose monohydrate, microcrystalline cellulose, croscarmellose sodium, magnesium stearate, red iron oxide (E172) (for the 10 mg strength), yellow iron oxide (E172) (for the 20 and 40 mg strengths) and brilliant blue FCF aluminium lake (E133) (for the 40 mg strength).

What Pravat looks like and contents of the pack
10 mg:
Light pink, round, unscored tablet, engraved 'APO' on one side and 'PRA' over '10' on the other side.
20 mg:
Off-white to light yellow, round, unscored tablet, engraved "APO" on one side and "PRA" over "20" on the other side
40 mg:
Light green, round, unscored tablet, engraved "APO" on one side and "PRA" over "40" on the other side.

The tablets are available in PVC/PVAC/Aluminium blisters containing 4, 10, 14, 20, 28, 30, 50, 56, 98, 100, 200 tablets.

Not all pack-sizes may be marketed.

Marketing Authorisation Holder

Apotex Europe BV
Darwinweg 20,
Leiden, 2333 CR,
Netherlands

Manufacturer
Apotex Nederland B.V., Archimedesweg 2, 2333 CN Leiden, The Netherlands

This medicinal product is authorised in the Member States of the EEA under the following names:

Ireland:	Pravat
Italy:	Pravastatina DOC Generici
Netherlands:	Pravastatinenatrium Apotex
Spain:	Pravastatina Cinfa

This leaflet was last revised in ~~July 2015~~June 2016