

PACKAGE LEAFLET: INFORMATION FOR THE USER

Pravastatin, 10 mg, tablets

Pravastatin, 20 mg, tablets

Pravastatin, 40 mg, 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 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 becomes 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 is and what it is used for
2. Before you take Pravastatin
3. How to take Pravastatin
4. Possible side effects
5. How to store Pravastatin
6. Further information

1. WHAT PRAVASTATIN IS AND WHAT IT IS USED FOR

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. BEFORE YOU TAKE PRAVASTATIN

Do not take Pravastatin if:

- you are allergic (hypersensitive) to pravastatin sodium or any of the other ingredients of Pravastatin (see section 6 - further information)
- you are breast-feeding
- you are pregnant or there is a possibility that you may become pregnant
- you have or have had liver problems.

Take special care with Pravastatin 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.

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.

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

- Have severe respiratory failure

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.

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).

Taking other medicines:

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

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 Pravastatin during pregnancy and/or breastfeeding. Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines:

Pravastatin 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.

Important information about some of the ingredients of Pravastatin

Pravastatin contains lactose monohydrate. If you have been told that you do not tolerate certain kinds of sugar, 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 about how much medicine to take or when to take it.

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 usual dose is 10 – 40 mg taken once a day, at bedtime.

Children (8-13 years): with heterozygous familial hypercholesterolaemia. The usual 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 Pravastatin 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 Pravastatin:

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 Pravastatin:

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, Pravastatin 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

These side effects occur very rarely.

Uncommon (affecting more than 1 person in 1000 but less than 1 in 100)

- 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 (affecting less than 1 person in 10000 including isolated reports)

- 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.

Frequency unknown:

- 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.

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

5. HOW TO STORE PRAVASTATIN

- Keep out of the reach and sight of children
- Store below 25 °C
- 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 stated on the carton. 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 contains

Pravastatin 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 Pravastatin 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 and Manufacturer

<[To be completed nationally]>

This leaflet was last approved in May 2012