

PRAVAFEN[®] Hard Capsules

Consumer Medication Information Leaflet (RiMUP)

Pravastatin Sodium 40mg & Fenofibrate 160mg

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What Pravafen is used for

The name of your medicine is Pravafen. It contains two active substances: pravastatin and fenofibrate. Both are cholesterol/lipid modifying medicines.

Pravafen is used in addition to low fat diet in adults

- To lower the level of your 'bad' cholesterol (LDL cholesterol). It does this by lowering the level of total cholesterol, and fatty substances called triglycerides in the blood.
- To raise the level of your 'good' cholesterol (HDL cholesterol).

Pravafen is used if you are a patient with an elevated risk for heart disease and need to improve cholesterol and triglycerides fat levels in your blood when your 'bad' cholesterol levels are being adequately controlled with pravastatin alone (a statin, a cholesterol-lowering medicine).

How Pravafen works

Cholesterol is one of several fats found in your blood. Your total cholesterol is made up mainly of LDL and HDL cholesterol.

LDL cholesterol is often called 'bad' cholesterol because it can build up in the walls of your arteries and form plaque. Over time, this plaque build-up can lead to a clogging of your arteries. This clogging can slow or block blood flow to vital organs such as the heart and brain. When the blood flow is blocked, the result can

be a heart attack or stroke.

HDL cholesterol is often called 'good' cholesterol because it helps keep the 'bad' cholesterol from building up in the arteries and because it protects against heart disease.

Triglycerides are another fat in your blood. They may raise your risk of having heart problems.

In most people, there are no signs of cholesterol problems at first. Your doctor can measure your cholesterol with a simple blood test. Visit your doctor regularly to keep track of your cholesterol level.

Before you use Pravafen

When you must not use it

Do not take Pravafen if

- You are allergic (hypersensitive) to fenofibrate, pravastatin, or any of the other ingredients of Pravafen (see section 6: Further information).
- You suffer from liver disease.
- You are under 18 years old.
- You suffer from kidney disease.
- You have had photoallergy (allergic reaction caused by sunlight or exposure to UV light) or phototoxic reactions (damage to skin caused by exposure to sunlight or UV light) during treatment with fibrates (lipid-modifying medicines) or ketoprofen (an anti-inflammatory medicine that can be used orally or on the skin for muscle and bone disorders, and orally for gout or period pain)
- You suffer from gallbladder disease.
- You suffer from pancreatitis (inflammation of the pancreas leading to abdominal pain)
- You are pregnant or breast-feeding.
- You have a history of muscle problems during treatment with cholesterol-controlling medicines called 'statins' (such as

simvastatin, atorvastatin, pravastatin or rosuvastatin), fibrates (such as fenofibrate and bezafibrate), gemfibrozil, or nicotinic acid.

Do not take Pravafen if any of the above applies to you. If you are not sure, talk to your doctor or pharmacist before taking Pravafen.

Children

Do not take Pravafen if you are under 18 years old

Before you start to use it

Before you take Pravafen you should tell your doctor if you have or have had any medical problems.

- Tell your doctor about all your medical conditions including allergies.
- Tell your doctor if you drink large amounts of alcohol (see below section Taking Pravafen with food and drink) or have ever had liver disease.
- Your doctor should do a blood test before you start taking Pravafen. This is to check how well your liver and your kidneys are working.
- Your doctor may also want you to have blood tests to check how well your liver is working after you start taking Pravafen.
- 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 **Side effects**).

Check with your doctor or pharmacist before taking Pravafen if you have severe respiratory failure,

e.g. you have breathing problems including, persistent non-productive cough, deterioration in general

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health like fatigue (tiredness), weight loss and/or shortness of breath or fever.

If you feel any of these symptoms you should stop taking Pravafen and inform your doctor.

Pregnancy and breast-feeding

Ask your doctor or pharmacist for advice before taking any medicine.

Do not take Pravafen if you are pregnant or trying to get pregnant or think you may be pregnant.

If you plan to become pregnant or become pregnant, inform your doctor immediately. The medicine should be discontinued because of the potential risk to the foetus.

Do not take Pravafen if you are breast-feeding.

Driving and using machines

Pravafen 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.

Important information about some of the ingredients of Pravafen

Pravafen contains a sugar called lactose. If you have been told by your doctor that you have intolerance to some sugars, contact your doctor before taking this medicine.

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. It is important that you inform your doctor if you are already being treated with any of the following:

- Bile acid resins such as colestyramine/colestipol (a medicine for lowering cholesterol), because it affects the way Pravafen works.
- Ciclosporin (a medicine often

used in organ transplant patients).

- Medicines to prevent blood clots, such as warfarin, fluindione, phenprocoumon or acenocoumarol (anticoagulants)
- Antibiotic such as erythromycin or clarithromycin to treat infections caused by bacteria.
- Fusidic acid: 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 Pravafen. Taking Pravafen with fusidic acid may rarely lead to muscle weakness, tenderness or pain (rhabdomyolysis). Also see section 4 of this leaflet.
- Colchicine (a medicine commonly used to treat gout)
- Gemfibrozil and nicotinic acid (medicine often used as lipid lowering agents) Also see section 4 of this leaflet.
- Glecaprevir/pibrentasvir (used to treat hepatitis C virus infection) because it can increase some adverse events including muscle problems.
- A particular class of medicines to treat diabetes (such as rosiglitazone, pioglitazone)

Taking Pravafen with food and drink

- Always take Pravafen with food as Pravafen is less well absorbed from an empty stomach.
- 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.

If you are not sure about this, please follow your doctor's advice.

How to use Pravafen

How much and when to use it

Always take Pravafen exactly as your

doctor has told you. You should check with your doctor or pharmacist if you are not sure.

- Before starting taking Pravafen, you should be on a diet to lower your cholesterol.
- You should keep to this diet while taking Pravafen

The usual dose for adults is one capsule taken daily during the evening meal. Swallow the capsule with water. It is important to take the capsule with food, as it won't work as well if your stomach is empty.

When your doctor has prescribed Pravafen along with colestyramine or any other bile acid binding resins (medicines for lowering cholesterol), take Pravafen 1 hour before, or 4 to 6 hours after the resin. This is because colestyramine or other bile acid binding resins frequently reduce the absorption of medicines when taken too closely together and so may impede the absorption of Pravafen. If you take indigestion remedies (used to neutralise acid in your stomach), take Pravafen 1 hour after.

How long to use it

Do not stop taking Pravafen without first discussing it with your doctor.

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

If you forget to use it

Do not take a double dose to make up for a forgotten dose, just take your normal amount of Pravafen at the usual time the next day.

If you use too much (overdose)

Please contact your doctor or pharmacist.

While you are using Pravafen

Things you must and must not do

Contact your doctor immediately if you experience unexplained muscle pain, tenderness, or weakness. This is because, on rare occasions, muscle problems can be serious, including muscle breakdown resulting in

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kidney damage, and very rarely deaths have occurred. The risk of muscle breakdown is greater in certain patients.

Tell your doctor if any of the following applies to you:

- Liver or kidney problems
- Thyroid problems
- You are more than 70 years old
- You have ever had muscle problems during a treatment with cholesterol-lowering medicines such as a statin, fibrate, gemfibrozil or nicotinic acid
- You are taking or, in the last 7 days, have taken or been given a medicine called fusidic acid (a medicine for bacterial infection)
- You are having gout and taking colchicines (a medicine used to treat gout)
- You or your close family members have a hereditary muscle disorder
- You have alcohol problems (regularly drinking large amounts of alcohol)

Things to be careful of

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.

Side effects

Like all medicines, Pravafen can cause side effects, although not everybody gets them. If the side-effects don't go away after a few days, or you feel unwell in any other way, talk to your doctor before you take your next dose.

Tell your doctor straight away if you have any unexplained muscular pain or cramps, tenderness, or weakness. This is because on very

rare occasions, muscle problems can be serious, including muscle breakdown resulting in kidney damage, and very rarely deaths have occurred.

Sudden severe allergic reactions including swelling of the face, lip, tongue or wind pipe which can cause great difficulty in breathing.

This is a very rare reaction which can be serious if it occurs. You should tell your doctor immediately if it happens.

The following side effects are important and will require immediate action.

Common side effects (may affect up to 1 in 10 people)

- Digestive effects: gastric or intestinal disorders (abdominal pain, nausea, vomiting, diarrhoea and flatulence, constipation, dry mouth, upper abdominal pain with bloating (dyspepsia), burping (eructation)).
- Effects on liver: raised serum transaminases.

Uncommon side effects (may affect up to 1 in 100 people)

- Abnormal heartbeat (palpitations), formation of blood clots in veins (deep vein thrombosis) and blockage of the lung arteries by blood clots (pulmonary embolism)
- Rashes, skin rash, itching, hives or reactions to sunlight or exposure to UV light (photosensitivity reactions), scalp/hair abnormality (including hair loss)
- Effects on nervous system: dizziness (sensation of unsteadiness), headache, sleep disturbances (including difficulty sleeping and nightmares), pins and needles sensation (paresthesia).
- Muscle and joint pain (myalgia, arthralgia), back pain,

alterations in some laboratory blood tests for muscle function.

- Problems with sight such as blurred or double vision.
- Kidney problems (increased or decreased levels of certain enzymes within the body seen in a test) bladder problems (painful or frequent urination, having to pass water at night), sexual dysfunction.
- Tiredness, weakness, influenza-like illness.
- Hypersensitivity.
- Increased blood cholesterol, increased blood triglycerides, increased LDL, increased gamma-glutamyl transferase (various liver enzymes), liver pain (upper right abdominal pain with or without pain in the back), increased weight.
- Obesity.
- Muscle inflammation (myositis), muscular cramps and weakness.

Rare side effects (may affect up to 1 in 1,000 people)

- Decrease in haemoglobin (oxygen-carrying pigment in blood) and leukocytes (white blood cells).

Very rare side effects (may affect up to 1 in 10,000 people)

- Inflammation of the liver (hepatitis), symptoms of which may be mild yellowing of the skin and whites of the eyes (jaundice), abdominal pain and itching.
- Muscle breakdown (rhabdomyolysis), some cases of tendon problems, sometimes complicated by rupture.
- A condition characterised by an inflammation of the muscles and the skin (dermatomyositis).
- Skin rash, possibly with pain in the joints (Erythematous lupus like syndrome).
- Tingling and numbness (peripheral polyneuropathy).

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Side effects of unknown frequency (frequency cannot be estimated from the available data)

- Muscle weakness that is constant
- Skin rash (lichenoid eruption)
- Myasthenia gravis (a disease causing general muscle weakness including in some cases muscles used when breathing).
- Ocular myasthenia (a disease causing eye muscle weakness).

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.

Possible side effects reported with some statins (same type of cholesterol-lowering medicines as pravastatin)

- Memory loss
- Depression
- Breathing problems including persistent cough/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 gets serious, or if you notice any side effects not listed in this leaflet, please tell your

doctor or pharmacist.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website portal.bpfk.gov.my (Consumers → Reporting).

Storage and disposal of Pravafen

Store below 30°C.

Keep out of the reach and sight of children.

Do not use Pravafen after the expiry date which is stated on the carton and the blister/bottle after EXP.

This medicine does not require any special storage conditions.

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.

Product description

What it looks like

The capsules are hard gelatine capsule with olive cap and light green body containing a waxy white beige mass and a tablet.

The capsules are supplied in opaque white plastic bottles containing 30 capsules.

Ingredients

- The active substances are fenofibrate and pravastatin sodium. Each hard capsule contains 40 mg pravastatin sodium and 160 mg fenofibrate.
- The other ingredients are:
 - capsule content: lactose monohydrate, cellulose microcrystalline, ascorbyl palmitate, povidone, sodium starch glycolate, magnesium stearate, talc, triacetin, sodium hydrogen carbonate, lauroyl macroglycerides, hydroxypropylcellulose, macrogol 20 000.
 - capsule shell: gelatine, indigo carmine (E132), black iron oxide (E172), titanium dioxide (E171), yellow iron oxide (E172).

Product Registration Number:

MAL 14055417AZ

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Product registration holder

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