

PRAVASTATIN TABLETS

Contains the active ingredient Pravastatin sodium

Consumer Medicine Information

What is in this leaflet

Please read this leaflet carefully before you start using PRAVASTATIN.

This leaflet answers some common questions about PRAVASTATIN. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist

All medicines have risks and benefits. Your doctor has weighed the risks of you taking PRAVASTATIN against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What this medicine is used for

PRAVASTATIN contains the active ingredient pravastatin sodium.

This medicine belongs to a group of medicines called HMG-CoA reductase inhibitors. It works by reducing the cholesterol biosynthesis

PRAVASTATIN is used to:

- reduce the risk of heart attacks, reduce the need for treatment related to heart blood vessels and to reduce deaths related to the heart blood vessels in patients with high cholesterol levels who already follow an amended diet
- treat high levels of cholesterol

where measures to diet and lifestyle changes were not sufficient

- reduce the incidences of further heart diseases in male patients less than 75 years of age with pre-existing diseases related to
- the heart blood vessels when taken in addition to dietary amendments
- reduce the incidences of further heart diseases and reduce the need for treatment related to heart blood vessels in patients who have had such problems
- reduce transplant rejection and to improve survival rates in heart or kidney transplant patients who are also being given immunosuppressive medicine

Your doctor may have prescribed PRAVASTATIN for another reason.

Cholesterol is a naturally occurring substance in the body necessary for normal growth. However, when you have high levels of cholesterol it may 'stick' to the inside of your blood vessels instead of being carried to the parts of the body where it is needed. Over time, this can form hard areas (called plaques) on the walls of your blood vessels, making it more difficult for the blood to flow. This blocking of your blood vessels can lead to heart disease (such as heart attack and angina), and stroke. Other factors including high blood pressure, high blood sugar (diabetes), increased weight, lack of exercise and smoking further add to the risk of heart disease. High cholesterol levels in the blood can be brought down and kept down with dietary modifications, exercise and medicines.

Ask your doctor if you have any questions about why

PRAVASTATIN has been prescribed for you.

This medicine is available only with a doctor's prescription.

There is no evidence that this medicine is addictive

Use in children

There is not enough information to recommend the use of PRAVASTATIN in children under the age of 18 years.

Before you take this medicine

When you must not take it

Do not use PRAVASTATIN if:

- **You are hypersensitive to, or have had an allergic reaction to pravastatin or any of the ingredients listed at the end of this leaflet.**

Symptoms of an allergic reaction may include: cough, shortness of breath, wheezing, difficulty breathing or tightness in chest; swelling of the face, lips, tongue, throat or other parts of the body; rash, itching or hives on the skin; fainting; or hay fever-like symptoms.

If you think you are having an allergic reaction, do not take any more of the medicine and contact your doctor

immediately or go to the Accident and Emergency department at the nearest hospital.

- **Do not take this medicine if you are pregnant or if you may become pregnant.**

It may affect your developing baby if you take it during pregnancy.

- **Do not breast-feed if you are taking this medicine.**

The active ingredient in PRAVASTATIN passes into breast milk and there is a possibility that your baby may be affected

- **Do not take this medicine if you take fusidic acid**, a medicine used to treat bacterial infections.

- **Do not take this medicine if you have a liver disease or any unexplained abnormal blood test results for liver function.**

- **The expiry date (EXP) printed on the pack has passed.**

If you take it after the expiry date has passed, it may have no effect at all, or worse, there may be an entirely unexpected effect.

- **The packaging is torn, shows signs of tampering or it does not look quite right.**

If you are not sure whether you should start using PRAVASTATIN, talk to your doctor.

Before you start to take it

Tell your doctor or pharmacist if:

You have allergies to:

- any other medicines
- any other substances, such as foods, preservatives or dyes.

You have or have had any medical conditions, especially the following:

- liver disease
- kidney disease
- heavy alcohol consumption
- muscle pain, tenderness or weakness
- poorly controlled diabetes
- high blood pressure
- high blood lipid levels
- homozygous familial hypercholesterolemia

You are currently pregnant or you plan to become pregnant.

Do not take this medicine while pregnant until you and your doctor have discussed the risks and benefits involved.

You are currently breastfeeding or you plan to breast-feed. Do not take this medicine whilst breastfeeding.

PRAVASTATIN passes into breast milk and may affect your baby.

If you have not told your doctor about any of the above, tell them before you start using PRAVASTATIN.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food shop. You should also tell any health professional who is prescribing a new medication for you that you are taking PRAVASTATIN.

Some medicines may interfere with PRAVASTATIN. These include:

- medicines used to treat abnormal blood lipid levels such as gemfibrozil, cholestyramine and colestipol
- Ciclosporin, a medicine used to treat inflammatory and autoimmune diseases

- Antacids, medicines that neutralize acid in the stomach
- Macrolides are natural products that have antibiotic or antifungal activity
- Propranolol belongs to a group of medicines called beta-blockers. It helps to decrease anxiety and relieve tremors. It is also used to help prevent migraine, heart-related chest pain (angina), and bleeding in the stomach caused by high blood pressure in the liver (portal hypertension)
- Bile acid sequestrants bind to bile acids in the intestine and increase the excretion of bile acids in the stool. This reduces the amount of bile acids returning to the liver and forces the liver to produce more bile acids to replace the bile acids lost in the stool
- Digoxin is a medication used to treat various heart conditions

These medicines may be affected by PRAVASTATIN, or may affect how well it works. You may need different amounts of your medicine, or you may need to take different medicines.

Other medicines not listed above may also interact with PRAVASTATIN.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking PRAVASTATIN.

How to take this medicine

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

The label should be carefully read.

How much to take

The recommended dose for adults is 10 mg to 40 mg once daily.

Before taking PRAVASTATIN you will have been placed on a cholesterol-lowering diet and your blood lipid levels will have been assessed.

Make sure you continue with your recommended diet, exercise and other lifestyle changes while on your medicine.

Children

PRAVASTATIN should not be given to children.

Do not stop taking your medicine or change your dosage without first checking with your doctor.

How to take it

Take this medicine orally. Take with or without food and swallow the tablet(s) whole with a full glass of water.

When to take it

Take your medicine once a day in the evening before bedtime or as your doctor has instructed you to.

Taking it at the same time each day will have the best effect and will also help you remember when to take it.

It does not matter if you take this medicine before or after food.

If you need to take a medicine used to treat abnormal blood lipid levels such as cholestyramine or colestipol, take it at least 4 hours before or 1 hour after your dose of PRAVASTATIN.

How long to take it

Continue taking your medicine for as long as your doctor tells you.

This medicine helps to control your condition, but does not cure it. It is important to keep taking your medicine even if you feel well.

If you forget to take it

If it is almost time to take your next dose, skip the dose you missed and take your next dose at the usual time.

Otherwise, take it as soon as you remember, and then go back to taking your tablets as you would normally.

Do not take a double dose to make up for the dose that you missed.

This may increase the chance of you getting an unwanted side effect

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints to help you remember.

If you take too much (overdose)

If you think that you or anyone else may have taken too much of this medicine, immediately telephone your doctor or the National Poisons Centre (telephone 0800 POISON or 0800 764 766) for advice, or go to Accident and Emergency at the nearest hospital.

Do this even if there are no signs of discomfort or poisoning.

If any of these occur, you should get medical attention immediately.

While you are taking this medicine

Things you must do

If you are about to be started on any new medicine, tell your doctor and pharmacist that you are taking PRAVASTATIN.

Take your medicine exactly as your doctor has prescribed.

Tell all doctors, dentists and pharmacists who are treating you that you are taking this medicine.

Tell your doctor (immediately) if you become pregnant while you are taking it.

Tell your doctor if you are breastfeeding or are planning to breastfeed while you are taking it.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine. It may affect other medicines used during surgery

Always discuss with your doctor any problems or difficulties during or after taking PRAVASTATIN.

If you are about to have any blood tests, tell your doctor that you are taking this medicine. It may interfere with the results of some tests.

Keep all of your doctor's appointments so that your progress can be checked. Your doctor may do some tests (e.g.g tests for liver function, blood lipid levels and/or blood sugar levels) from time to time to make sure the medicine is working and to prevent unwanted side effects. Tell your doctor if for any reason, you have not taken your medicine exactly as prescribed. Otherwise

your doctor may think that it was not effective and change your treatment unnecessarily.

Keep enough PRAVASTATIN to last weekends and holidays.

Things you must not do

Do not give PRAVASTATIN to anyone else, even if they have the same condition as you.

Do not take your medicine to treat any other condition unless your doctor tells you to.

Do not stop taking your medicine, or change the dosage, without first checking with your doctor.

Do not take any other medicine while you are taking PRAVASTATIN without first telling your doctor.

Do not take PRAVASTATIN for a longer time than your doctor has prescribed.

Things to be careful of

Be careful driving or operating machinery until you know how PRAVASTATIN affects you.

This medicine may cause dizziness or may affect vision in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

Things that would be helpful to your condition

Some self-help measures suggested below may help your condition. Your doctor or pharmacist can give you more information about these measures.

Eat a healthy diet, which includes plenty of fresh vegetables, fruit,

bread, cereals and fish. Also eat less fat and sugar.

Regular exercise helps reduce blood pressure and helps the heart get fitter, but it is important not to overdo it. Walking is good exercise, but try to find a route that is fairly flat. Before starting any exercise, ask your doctor about the best kind of programme for you.

Your doctor may advise you to stop or at least cut down smoking.

Your doctor may suggest losing weight to help lower your blood pressure and help lessen the amount of work your heart has to do. Some patients may need to see a dietician to help lose weight.

Possible side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking PRAVASTATIN or if you have any questions or concerns

This medicine helps most people with increased blood cholesterol levels, but it may have unwanted side effects in a few people

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the adverse effects.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor if you notice any of the following and they worry you:

- rash
- itching
- impaired sexual function
- impaired sex drive
- nausea / vomiting

- an uncomfortable feeling in the stomach or belching after eating / heartburn
- excessive gas in the stomach or bowel
- constipation
- diarrhoea
- abdominal pain
- bloating and swelling in the belly area
- fatigue
- changes in weight
- weakness
- dizziness
- headache
- sleep disturbances, nightmares
- depression
- anxiety / nervousness
- numbness
- urination abnormalities
- impaired vision
- eye irritations
- impaired hearing
- impaired taste
- weak neck with inability to move
- shaking or tremor
- dizziness
- impaired memory
- symptoms of sunburn which may occur more quickly than usual
- flushing
- loss of appetite
- unusual hair loss
- breast enlargement in men
- memory loss
- diabetes mellitus (start or worsening)

This list includes the most common side effects. Mostly, these are mild and transient.

Tell your doctor immediately if you notice any of the following:

- swelling of the ankles, feet or legs
- flu-like symptoms such as

- high temperature, sore throat, runny nose, cough and chills
- feeling of tension or fullness in the nose, cheeks and behind your eyes
 - sore throat and discomfort when swallowing
 - painful and/or swollen joints
 - fever
 - chills

The above list includes serious side effects that may require medical attention.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- a pain or uncomfortable feeling in the chest, often spreading to arms or neck and sometimes to the shoulders and back
- heart attack
- changes in the frequency of heart beat
- difficulties with breathing
- muscle pain, tenderness or weakness
- signs of allergy such as shortness of breath, wheezing or difficulty breathing, swelling of the face, lips, tongue or other parts of the body, rash, itching or hives on the skin
- unusual bleeding or bruising
- yellowing of the skin and eyes, light coloured bowel motions, dark coloured urine

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation

Tell your doctor or pharmacist if you notice anything that is making you feel unwell

Some side effects (for example, changes in thyroid function, cholesterol level, blood pressure, kidney diseases, liver diseases or changes in blood cell counts) can only be found when your doctor does tests from time to time to check your progress.

Other side effects not listed above may also occur in some patients. Tell your doctor if you notice any other effects.

Ask your doctor or pharmacist if you do not understand anything in this section.

Do not be alarmed by this list of possible adverse effects. You may not experience any of them.

Storage and disposal

Keep your medicine in its original packaging until it is time to take it.

If you take your medicine out of its original packaging it may not keep well.

Keep your medicine in a cool dry place where the temperature stays below 25°C.

Do not store any medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking this medicine or the expiry date has passed, your pharmacist can dispose of the remaining medicine safely.

Product description

What it looks like

PRAVASTATIN 10 mg tablets are light pink, round, unscored tablets,

imprinted “APO” on one side and “PRA” over “10” on the other side.

PRAVASTATIN 20 mg tablets are off-white to light yellow, round, unscored tablets, imprinted “APO” on one side and “PRA” over “20” on the other side.

PRAVASTATIN 40 mg tablets are light green, round, unscored tablets, imprinted “APO” on one side and “PRA” over “40” on the other side

Available in

- blister packs of 30 tablets
- bottles of 30, 100 or 500 tablets.

*Not all presentations or strengths may be marketed.

Ingredients

Each tablet contains 10mg, 20mg or 40mg of the active ingredient pravastatin sodium.

It also contains the following inactive ingredients:

- Lactose monohydrate
- Microcrystalline Cellulose
- Magnesium Stearate
- Croscarmellose Sodium
- Iron oxide red (in 10 mg tablets)
- Iron oxide yellow (in 20 mg and 40 mg tablets)
- Brilliant blue FCF (in 40 mg tablets)

This medicine is gluten free.

This medicine contains lactose.

Sponsor

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