

NEW ZEALAND CONSUMER MEDICINE INFORMATION

PRAVASTATIN MYLAN

Pravastatin sodium Tablets 20 mg and 40 mg



What is in this leaflet

Please read this leaflet carefully before you start taking PRAVASTATIN MYLAN.

This leaflet answers some common questions about PRAVASTATIN MYLAN.

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 MYLAN 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 PRAVASTATIN MYLAN is used for

PRAVASTATIN MYLAN 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

PRAVASTATIN MYLAN contains the active ingredient pravastatin sodium. It belongs to a group of medicines called HMG-CoA reductase inhibitors.

It works by reducing the cholesterol biosynthesis.

Your doctor may have prescribed this medicine 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 this medicine has been prescribed for you.

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

This medicine is not addictive.

There is not enough information to recommend the use of this medicine for children under the age of 18 years.

Before you take PRAVASTATIN MYLAN

When you must not take it

Do not take PRAVASTATIN MYLAN if you have an allergy to:

- any medicine containing pravastatin
- lactose
- any of the ingredients listed at the end of this leaflet

Some of the symptoms of an allergic reaction may include: 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.

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 MYLAN 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.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering. If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any of the following medical conditions:

- 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

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

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including medicines 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 MYLAN.

Some medicines may interfere with PRAVASTATIN MYLAN. 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

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

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

How to take PRAVASTATIN MYLAN

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

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the box, ask your doctor or pharmacist for help.

How much to take

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

Before taking PRAVASTATIN MYLAN 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.

How to take it

Swallow the tablets 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. It 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 MYLAN.

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 for your next dose, skip the dose you missed and take your next dose when you are meant to.

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

While you are taking PRAVASTATIN MYLAN

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 MYLAN.

Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.

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.

If you become pregnant while taking this medicine, tell your doctor immediately.

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. 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.

Things you must not do

Do not take PRAVASTATIN MYLAN to treat any other complaints unless your doctor tells you to.

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

Do not stop taking your medicine or lower the dosage without checking with your doctor.

Things to be careful of

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

In case of overdose

If you take too much (overdose)

Immediately telephone your doctor or the National Poisons Centre (telephone 0800 POISON or 0800 764 766), or go to accident and emergency at your nearest hospital, if you think that you or anyone else may have taken too much PRAVASTATIN MYLAN. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking PRAVASTATIN MYLAN.

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 side effects.

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

Tell your doctor or pharmacist 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
- 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

The above list includes the usually mild and short-lived effects.

Tell your doctor as soon as possible 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.

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

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.

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

After taking PRAVASTATIN MYLAN

Storage

Keep your tablets in the pack until it is time to take them.

If you take the tablets out of the pack they may not keep well.

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

Do not store PRAVASTATIN MYLAN or any other 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, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

PRAVASTATIN MYLAN 20 mg tablets are yellow coloured, rounded, rectangular shaped, biconvex uncoated tablets debossed with 'PDT' on one side and '20' on the other side.

PRAVASTATIN MYLAN 40 mg tablets are yellow coloured, rounded, rectangular shaped, biconvex uncoated tablet debossed with 'PDT' on one side and '40' on the other side.

PRAVASTATIN MYLAN is available in packs of 28 tablets.

Ingredients

Active ingredient:

PRAVASTATIN MYLAN contains 20 mg or 40 mg of pravastatin as the active ingredient.

Inactive ingredients:

Pravastatin Mylan also contains:

- lactose monohydrate
- microcrystalline cellulose
- croscarmellose sodium
- povidone
- magnesium oxide light
- magnesium stearate
- iron oxide yellow

This medicine does not contain sucrose, gluten, tartrazine or any other azo dyes.

If you want to know more

Should you have any questions regarding this product, please contact your pharmacist or doctor.

Who supplies this medicine

PRAVASTATIN MYLAN is supplied in New Zealand by:

Mylan New Zealand Ltd,
PO Box 11183,
Ellerslie,
Auckland
NEW ZEALAND

Telephone: (09) 579 2792

Date of Preparation

21 April 2020
(Based on datasheet dated 7 April 2020)