

# Pravastatin sodium 10 mg, 20 mg and 40 mg tablets

## Package leaflet: Information for the user

The name of your medicine is Pravastatin sodium 10 mg, 20 mg or 40 mg tablets, which will be referred to as Pravastatin throughout this leaflet

**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 Pravastatin is and what it is used for
2. What you need to know before you take Pravastatin
3. How to take Pravastatin
4. Possible side effects
5. How to store Pravastatin
6. Contents of the pack and other information

### 1 What Pravastatin is and what it is used for

Pravastatin belongs to a group of drugs called statins (or HMG-CoA reductase inhibitors). These reduce the amount of cholesterol and triglycerides (fatty substances) in your blood.

Pravastatin is used:

- to reduce your risk in the future of developing coronary heart disease or having a heart attack or stroke. If you have raised levels of cholesterol in your blood but do not have coronary heart disease. If you are at risk of developing coronary heart disease including the following risk factors: if you smoke, if you are overweight, if you have high blood sugar levels, if you have high blood pressure or if you take little exercise.
- to reduce your risk of having a further heart attack or stroke, if you have already had a heart attack or have unstable angina (pains in the chest)
- to reduce increased lipid levels (level of fats in the blood), if you have had an organ transplant and are taking medication to stop your body rejecting the transplant.

Some further information:

- Pravastatin is used to lower high levels of “bad” cholesterol and to raise the levels of “good” cholesterol in the blood when changes to diet and exercise have failed to adequately do this. While cholesterol is vital for the normal functioning of the body, if the level in the blood becomes too high it can build up on the walls of the arteries. Eventually blood vessels can become blocked. This condition is called hardening of the arteries (atherosclerosis). This may lead to: chest pain (angina pectoris), when a blood vessel in the heart is partially blocked; a heart attack (myocardial infarction), when a blood vessel in the heart is completely blocked; a stroke (cerebrovascular accident), when a blood vessel in the brain is completely blocked. Only a small amount of cholesterol comes from our diet, the majority is made by our own livers. The body produces most cholesterol at night.
- Even though you may be on a low fat diet, your doctor has done some blood tests which show that you still have too much fat (including cholesterol) in your blood. A high cholesterol level is generally recognised as adding to the risk of heart disease. Additional factors such as existing heart disease, high blood pressure, diabetes, being overweight, lack of exercise and smoking can also greatly increase the risk of the development or progression of heart disease

### 2 What you need to know before you take Pravastatin

**Do not take Pravastatin:**

- if you are allergic to Pravastatin or any of the other ingredients of this medicine (listed in section 6)
- if you have current liver problems
- if you are pregnant or there is a possibility that you may become pregnant or are breast feeding (see “pregnancy, breast-feeding and fertility”).

## Warnings and precautions

Talk to your doctor or pharmacist before taking Pravastatin:

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 4).

- if you have kidney problems
- if you are a child before puberty (puberty is the process of physical changes by which a child's body becomes an adult body capable of reproduction). In this case your doctor should properly evaluate the risk/benefit of treatment carefully before starting this medicine.
- if you are over 70 years of age
- if you have suffered with liver problems in the past
- if you have an underactive thyroid gland (hypothyroidism)
- if you have an hereditary muscle disorder or a family history of such problems
- if you have previously suffered from side effects

- affecting your muscles when taking another cholesterol lowering medicine such as a statin (HMG-CoA reductase inhibitor drugs) or a fibrate e.g. gemfibrozil
- if you feel any unexplained cramps or muscle pains during treatment, tell your doctor immediately
- if you have problems with alcohol abuse (regularly drinking large amounts of alcohol).
- 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 can lead to serious muscle problems (rhabdomyolysis).

If any of the above apply to you, your doctor will need to carry out a blood test before and possibly during your treatment. These blood tests will be used to evaluate your risk of muscle-related side effects.

Your doctor should do a blood test before you start taking Pravastatin and if you have any symptoms of liver problems while you take Pravastatin. This is to check how well your liver is working.

Your doctor may also want you to have blood tests to check how well your liver is working after you start taking Pravastatin.

Also talk to your doctor or pharmacist before taking Pravastatin:

- if you have severe respiratory failure.

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.

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.

## Other medicines and Pravastatin

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Including:

- a group of cholesterol lowering medicines called fibrates e.g. fenofibrate or gemfibrozil, a medicine which lowers the body's immune defences (ciclosporin an immunosuppressant used after an organ transplant), another medicine which lowers the level of cholesterol in your body (nicotinic acid (vitamin B3)), as these medicines can interfere with the way Pravastatin works in your body.
- drugs known as bile acid sequestrants (a class of drugs that prevents bile acids being reabsorbed from the digestive system, so promoting conversion of cholesterol into bile acids and lowers the level of fat in your blood) e.g. colestyramine, colestipol (please see section 3, If you are also taking a bile acid sequestrant)
- a medicine which treats infections caused by bacteria (the antibiotics erythromycin, clarithromycin or 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 Pravastatin. Taking Pravastatin 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 “vitamin 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.

Taking Pravastatin with any of these medicines can increase the risk of muscle problems:

- Colchicine (used to treat gout)
- Nicotinic acid (used to treat high blood cholesterol)
- Rifampicine (used to treat an infection called tuberculosis)
- Lenalidomide (used to treat a type of blood cancer called multiple myeloma)

## Pravastatin with food, drink and alcohol

- Keep alcohol intake to a minimum, if you want to drink then only have small quantities of alcohol whilst taking this medicine, and make sure you do not stop taking your medicine if you have an alcoholic drink one evening. If you are concerned about how much alcohol you can drink while you are taking this medicine, you should discuss this with your doctor.

## Pregnancy, breast-feeding and fertility

**Do not take Pravastatin:**

- if you are pregnant or breast-feeding (as this medicine passes into the mother's milk), or if you are planning to become pregnant
- if you are a woman who could become pregnant (unless you are using a reliable form of contraception other than the pill or other hormonal contraceptives). If you do become pregnant when taking Pravastatin, stop taking the tablets as soon as you become aware of it.

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

## Driving and using machines

- Pravastatin may cause dizziness blurred or double vision during treatment, if affected do not drive or operate machinery. Make sure you are fit to drive and use machines before attempting to do so.

## Pravastatin contains lactose

- Patients who are intolerant to lactose should note that Pravastatin tablets contain a small amount of



lactose. If your doctor has told you that you have an intolerance to some sugars, 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. Your doctor will have explained the importance of a low fat diet as well as taking Pravastatin and you should continue this diet over the full treatment period.

The tablets should be swallowed preferably with a glass of water. Pravastatin can be taken with or without food.

#### Adults and older people

- In the treatment of high levels of cholesterol and fats in the blood: the recommended dose is 10-40 mg once a day, preferably in the evening.
- In the prevention of heart and blood vessel diseases: the recommended dose is 40 mg once a day, preferably in the evening.

The maximum daily dose of 40 mg for Pravastatin should not be exceeded. Your doctor will tell you which dose suits you.

#### Following organ transplantation

Your doctor may prescribe a starting dose of 20 mg once a day. The dose may be adjusted up to 40 mg by your doctor.

If you are also taking a medicine which lowers the body's immune system (ciclosporin), your doctor may prescribe a starting dose of 20 mg once a day. The dose may be adjusted up to 40 mg by your doctor.

If you have the impression that the effect of this treatment is too strong or too weak, talk to your doctor or pharmacist.

#### Duration of treatment

Your doctor will indicate the duration of your treatment with Pravastatin. This medicine must be used very regularly and for as long as your doctor advises, even if it is for a very long time. Do not stop your treatment by yourself.

- **If you are also taking a bile acid sequestrant**, such as colestyramine or colestipol, Pravastatin should be taken at least one hour before or four hours after you have taken the bile acid sequestrant. This is because the absorption of Pravastatin can be affected by these medicines if taken too closely together.

#### Liver or kidney problems

If you have either liver or kidney problems your doctor may prescribe a lower dose.

#### Use in children and adolescents

##### Children adolescents (8-18 years of age) with a hereditary disease which increases the level of cholesterol in the blood:

The usual dose is 10 to 20 mg once a day between 8 and 13 years and from 10 to 40 mg once a day between 14 and 18 years.

#### If you take more Pravastatin than you should

If you (or someone else) swallow a lot of the tablets all together, or if you think a child has swallowed any of the tablets, contact your nearest hospital casualty department or your doctor immediately. Please take this leaflet, any remaining tablets, and the container with you to the hospital or doctor so that they know which tablets were consumed.

#### If you forget to take Pravastatin

If you forget to take a dose, take one as soon as you remember, unless it is nearly time to take the next one. Do not take a double dose to make up for a forgotten dose.

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

### 4 Possible side effects

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

#### Stop taking Pravastatin and tell your doctor immediately

- 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.
- If you have breathing problem including persistent cough and or/shortness of breath or fever

#### Tell your doctor immediately if you develop:

- Any unexplained or persistent muscle pain, tenderness, weakness, or cramps, especially, if at the same time you feel unwell or have a high temperature.
- In very rare cases, muscle problems can be serious (rhabdomyolysis) and can lead to a serious, life threatening kidney disease.

Effects on skin and hair: rashes

Pravastatin can cause some other side effects:

**Uncommon** (may affect up to 1 in 100 people):

- Insomnia
- Dizziness
- Tiredness
- Headache or sleep disturbances
- Blurred or double vision
- Indigestion
- Nausea
- Vomiting
- Stomach pain or discomfort
- Painful sensation in chest due to stomach acidity
- Diarrhoea
- Constipation
- Wind (flatulence)
- Itching

- Pimples
- Hives
- Rashes
- Scalp and Hair problems (including hair loss)
- Bladder problems (painful or more frequent urination, having to pass water at night)
- Sexual difficulties
- Muscle and joint pain

Very rare (may affect up to 1 in 10 000 people):

- Weakness, problems with touch including burning or tingling sensation or numbness, which may indicate damage to the nerves (especially if you use Pravastatin for a long time)
- A severe skin disease (lupus erythematosus-like syndrome)
- Inflammation of the liver or pancreas; jaundice (recognisable by a yellowing of the skin and of whites of the eyes);
- Very rapid death of liver cells (fulminant hepatic necrosis)
- Inflammation of tendons which may be complicated by rupture of tendons
- Increases in transaminases (a group of enzymes occurring naturally in the blood) which may be a sign of liver problems. Your doctor may want to perform tests periodically to check these.

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

- Muscle weakness that is constant
- Diabetes mellitus: Frequency will depend on the presence or absence of risk factors (fasting blood glucose at 5.6 mmol/L, BMI>30kg/m<sup>2</sup>, raised triglycerides, history of hypertension).
- Dermatomyositis (condition characterized by an inflammation of the muscles and the skin).
- Liver failure
- Myasthenia gravis (a disease causing general muscle weakness including in some cases muscles used when breathing).
- Ocular myasthenia (a disease causing eye muscle weakness).
- Muscle rupture

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.

Following side effects have been reported with some Statins (Frequency unknown):

- Nightmare
- Memory loss
- Depression
- Breathing problem 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.

#### 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 the Yellow Card Scheme at: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

### 5 How to store Pravastatin

Keep this medicine out of the sight and reach of children. This medicinal product does not require any special storage conditions.

Do not use this medicine after the expiry date that is stated on the carton. 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 Pravastatin Tablets contain:

- The active ingredient is Pravastatin sodium.
- The other ingredients are crospovidone, lactose monohydrate and magnesium stearate.

#### What Pravastatin Tablets look like and contents of the pack:

- The 10 mg tablets are white to off white, round biconvex tablets, scored on one side of the tablet, debossed "P" and "10" on the other side.
- The 20 mg tablets are white to off white, round biconvex tablets, scored on one side of the tablet, debossed "P" and "20" on the other side.
- The 40 mg tablets are white to off white capsule-shaped tablets, scored on one side of the tablet, debossed "P" on the other side.
- The tablets come in pack sizes of 20, 28, 50, 100 and 200 tablets.

Not all pack sizes may be marketed.

#### Marketing Authorisation Holder

Teva UK Limited, Ridings Point, Whistler Drive, Castleford, WF10 5HX, United Kingdom

#### Manufacturer

Teva Pharmaceutical Works Private Limited Company, Pallagi Street 13, H-4042, Debrecen, Hungary.

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