Package leaflet: Information for the user

Pravastatinenatrium ratiopharm 10 mg, tabletten
Pravastatinenatrium ratiopharm 20 mg, tabletten
Pravastatinenatrium ratiopharm 40 mg, tabletten
Pravastatin sodium

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

Pravastatin belongs to a group of medicines called statins (or HMG-CoA reductase inhibitors). It prevents the production of cholesterol by the liver and consequently reduces the levels of cholesterol and other fats (triglycerides) in your body. When there are excessive levels of cholesterol in the blood, the cholesterol accumulates on the walls of blood vessels and blocks them.

This condition is called hardening of the arteries or atherosclerosis and it 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.

This medicine is used in 3 situations:

<u>In the treatment of high levels of cholesterol and fats in the blood</u>
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.

<u>In the prevention of heart and blood vessel diseases</u>
- If you have high levels of cholesterol in your blood and risk factors favouring these diseases (if you smoke, are overweight, if you have high blood sugar levels or high blood pressure, if you take little exercise), Pravastatin is used to reduce the risk of you having heart and blood vessel diseases and to lower your risk of dying from these diseases.

- If you have already had a stroke or if you have pains in the chest (unstable angina), and even if you have normal cholesterol levels, Pravastatin is used to reduce the risk of you having another heart attack or stroke in the future, and to lower your risk of dying from these diseases.

<u>After organ transplants</u>
If you have had an organ transplant and receive medication to prevent your body rejecting the transplant, Pravastatin is used to reduce increased levels of fats in the blood.

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 are pregnant, trying to become pregnant or if you are breast-feeding (see Pregnancy and breast-feeding);
- if you have a liver disease (active liver disease);
- if several blood tests have shown abnormal functioning of your liver (increased levels of liver enzymes in the blood).

Warnings and precautions
Talk to your doctor or pharmacist before taking Pravastatin if you have or have had any medical problems such as:
- kidney disease;
- an underactive thyroid (hypothyroidism);
- a liver disease or alcohol problems (drinking large amounts of alcohol);
- muscle disorders caused by a hereditary disease;
- muscle problems caused by another medicine belonging to the statins group (HMG-CoA reductase inhibitor drugs) or one belonging to the group known as fibrates (see Taking other medicines).
- 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).

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.

The risk of muscle breakdown is greater in certain patients. Tell your doctor if any of the following applies to you.

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 you have suffered from any of these problems, or if you are older than 70 years, 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.

If you feel any unexplained cramps or muscle pains during treatment, tell your doctor immediately.

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.

Check with your doctor or pharmacist before taking Pravastatin if you
- Have severe respiratory failure

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

Taking Pravastatin with any of these medicines can increase the risk of muscle problems:
- a medicine which lowers the cholesterol level in the blood (fibrates, e.g. gemfibrozil, fenofibrate);

- a medicine which lowers the body's immune defences (ciclosporin);
- a medicine which treats the infections caused by bacteria (an antibiotic such as erythromycin or clarithromycin);
- 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.
- Colchicine (used to treat gout)
- Nicotinic acid (another medicine used to lower high blood levels of cholesterol)
- Rifampicin (used to treat an infection called tuberculosis)
- Lenalidomide (used to treat a type of blood cancer called multiple myeloma)
- a drug used to treat and prevent formation of blood clots called "vitamine 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.

If you are also using a medicine which lowers the level of fat in your blood (of the resin-type such as colestyramine or colestipol), this treatment 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**.

Pravastatin with food and drink
This treatment can be taken with or without food, with half a glass of water.
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.

Pregnancy and breast-feeding
Do not take Pravastatin during pregnancy. If you discover that you are pregnant, you should inform your doctor immediately.

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

Do not take Pravastatin if you intend to breast-feed as this treatment passes into the mother's milk.

Driving and using machines
Pravastatin 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.

Pravastatin contains Lactose and Sodium
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium- free'.

3. How to take Pravastatin

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Your doctor will advise you on a lowfat diet which you should continue over the full treatment period.

Pravastatin can be taken with or without food, with half a glass of water.

The recommended dose is
<u>Adults</u>

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

The maximum daily dose of 40 mg of pravastatin should not be exceeded. Your doctor shall tell you which dose suits you.

Children (8-13 years) and adolescents (14-18 years) with a hereditary disease which increases the level of cholesterol in the blood
The usual dose is 10-20 mg once a day between 8 and 13 years and from 10 to 40 mg once a day between 14 and 18 years.

After organ transplant
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 suffer from kidney or severe liver disease, your doctor may prescribe a lower dose of Pravastatin to you.

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 take more Pravastatin than you should
If you have taken too many tablets, or if someone accidentally swallows some, contact your doctor or the nearest hospital for appropriate advice.

If you forget to take Pravastatin
If you miss a dose, simply take your usual dose when it is next due. 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 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 (rhabdomylosis) and can lead to a serious, life-threatening kidney disease.

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 uncommon and may affect up to 1 in 100 people

- ***Effects on nervous system:*** dizziness, tiredness, headache or sleep disturbances, including insomnia;
- ***Effects on vision:*** blurred or double vision;
- ***Digestive effects:*** indigestion, nausea, vomiting, stomach pain or discomfort, diarrhoea or constipation and wind;
- ***Effects on skin and hair:*** itching, pimples, hives, rashes, scalp and hair problems (including hair loss);
- ***Urinary and genital effects:*** bladder problems (painful or more frequent urination, having to pass water at night) and sexual difficulties;
- ***Effects on muscles and joints:*** muscle and joint pain, inflammation of tendons which may be complicated by rupture of tendons.

The following side effects are rare and may affect up to 1 in 1,000 people

- Skin sensitivity to the sun

The following side effects are very rare and may affect up to 1 in 10,000 people

- ***Effects on nervous system:*** problems with touch including burning or tingling sensations or numbness which may indicate damage to nerves;
- ***Effects on skin:*** a severe skin disease (lupus erythematous-like syndrome);
- ***Effects on liver:*** 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)
- ***Effects on muscles and bones:*** inflammation of one or more muscles leading to pain or weakness in muscles (myositis or polymyositis or dermatomyositis); pain or weakness in muscles.
- ***Abnormal blood tests:*** 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.

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.

Possible side effects

- Nightmares
- Memory loss
- Depression
- Breathing problems including persistant 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.

Side effects of unknown frequency: Muscle weakness that is constant, liver failure, muscle rupture.
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.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in Appendix V. 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.

Do not use this medicine after the expiry date which is stated on the carton and blister after EXP. The expiry date refers to the last day of that month.

Do not store above 30°C. Store in the original package in order to protect from moisture.

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 contains

- The active substance is pravastatin sodium. Each tablet contains 10, 20 or 40 mg pravastatin sodium.
- The other ingredients are lactose, povidone (PVP K-30), crospovidone, calcium hydrogen phosphate (E341), sodium stearyl fumarate, cellulose microcrystalline (E460), croscarmellose sodium (E466),
  10 mg: red iron oxide (E172),
  20 mg: yellow iron oxide (E172),
  40 mg: quinoline yellow (E104), brilliant blue FCF (E133).

What Pravastatin looks like and contents of the pack

Tablet

10 mg:
Pink, mottled, round, shallow convex tablet, with breakline on both sides. The tablet can be divided into equal doses.

<Pravastatin 10 mg Tablets> are available in pack sizes of: 20, 28, 30, 50, 60, 84, 90 and 100 tablets and in hospital packs of 50 tablets.

Not all pack sizes may be marketed.

20 mg:
Light yellow, round, shallow convex tablet, with breakline on both sides. The tablet can be divided into equal doses.

<Pravastatin 20 mg Tablets> are available in pack sizes of 10, 20, 28, 30, 50, 60, 84, 90 and 100 tablets and in hospital packs of 50 tablets.

Not all pack sizes may be marketed.

40 mg:
Light green, round, shallow convex tablet, with breakline on both sides. The tablet can be divided into equal doses.

<Pravastatin 40 mg Tablets> are available in pack sizes of 14, 20, 28, 30, 50, 60, 84, 90 and 100 tablets and hospital packs of 50 tablets.

Not all pack sizes may be marketed.

Houder van de vergunning voor het in de handel brengen en fabrikant
Houder van de vergunning voor het in de handel brengen
Ratiopharm GmbH
Graf-Arco-Str. 3
89079 Ulm

Duitsland

Fabrikant
Pharmachemie B.V., Swensweg 5, 2031 GA Haarlem, Nederland
Teva Pharmaceutical Works Private Limited Company, Pallagi út 13, 4042 Debrecen, Hongarije
Teva Czech Industries s.r.o., Ostravská 29, č.p. 305, 747 70 Opava–Komárov, Tsjechië
Teva Pharma S.L.U., C/ Anabel Segura 11, Edificio Albatros B, 1ª planta, Alcobendas, 28108 Madrid, Spain.
Site address: C/ C, n° 4, Poligono Industrial Malpica, 50016 Zaragoza, Spanje
Merckle GmbH, Ludwig-Merckle-Str. 3, 89143 Blaubeuren, Duitsland

In het register ingeschreven onder
RVG 106528, Pravastatinenatrium ratiopharm 10 mg, tabletten
RVG 106529, Pravastatinenatrium ratiopharm 20 mg, tabletten
RVG 106530, Pravastatinenatrium ratiopharm 40 mg, tabletten

Dit geneesmiddel is geregistreerd in lidstaten van de EEA onder de volgende namen:

Duitsland:	Pravastatin-ratiopharm 10 mg Tabletten
	Pravastatin-ratiopharm 20 mg Tabletten
	Pravastatin- ratiopharm 40 mg Tabletten
Nederland:	Pravastatinenatrium ratiopharm 10 mg, tabletten
	Pravastatinenatrium ratiopharm 20 mg, tabletten
	Pravastatinenatrium ratiopharm 40 mg, tabletten
Portugal:	Pravastatina ratiopharm 10mg, 20mg, 40 mg Comprimidos
Spanje:	Pravastatina Teva-ratio 10 mg comprimidos EFG
	Pravastatina Teva-ratio 20 mg comprimidos EFG
	Pravastatina Teva-ratio 40 mg comprimidos EFG

Deze bijsluiter is voor het laatst goedgekeurd in augustus 2024.