

## Package leaflet: Information for the user

**Pravastatinenatrium 10 mg Pharmachemie, tabletten**  
**Pravastatinenatrium 20 mg Pharmachemie, tabletten**  
**Pravastatinenatrium 40 mg Pharmachemie, 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
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 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, when a blood vessel in the heart is completely blocked,
- a stroke, when a blood vessel in the brain is completely blocked.

This medicine is used in 3 situations:

#### In the treatment of high levels of cholesterol and fats in the blood

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.

#### In the prevention of heart and blood vessel diseases

- 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.
- 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.

#### After organ transplants

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

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.

Pravastatin may increase the risk of muscle related side effects in some patients, which results in muscle pain, tenderness and weakness. The doctor may perform a blood test to check the condition of your muscles before and after starting treatment with Pravastatin.

Talk to your doctor or pharmacist BEFORE taking Pravastatin if any of the following apply to you as you may have a greater risk of muscle related side effects:

- if you have a kidney disease;
- if you have an underactive thyroid (hypothyroidism);
- if you have a liver disease or alcohol problems (drinking large amounts of alcohol);
- if you have a muscle disorders caused by a hereditary disease;
- if you have had 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.
- if you are older than 70 years
- 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).

Some medicines may increase your risk of muscle related side effects, see “Other medicines and Pravastatin”.

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

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.

Statins, such as Pravastatin, may sometimes cause lung disease, especially when they are used over a long period of time. You should stop taking Pravastatin and contact your doctor if you develop shortness of breath, a dry, non-productive cough and your general health worsens, with tiredness, weight loss and fever.

### 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:

- fibrates, e.g. gemfibrozil, fenofibrate ( medicines which lower the cholesterol level in the blood );

- ciclosporin (a medicine which lowers the body's immune defences);
- antibiotics such as erythromycin or clarithromycin (a medicine which treats the infections caused by bacteria );
- colchicine (used to treat gout)
  - nicotinic acid (used to treat high blood cholesterol)
- rifampicin (used to treat an infection called tuberculosis)
- lenalidomide (used to treat a type of blood cancer called multiple myeloma)

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 need to take 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

### Adults

- 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.

### **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.

### **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.

### **If the following happens, stop taking the tablets and tell your doctor immediately or go to the casualty department at your nearest hospital:**

- an allergic reaction (swelling of the face or neck, muscle and joint pain, hives, fever, flushing, shortness of breath).

This is a very serious but rare side effect. You may need urgent medical attention or hospitalisation.

### **Contact your doctor as soon as possible and stop taking Pravastatin 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 this can progress to become a serious and potentially life threatening condition, called rhabdomyolysis.

*The following side effects are uncommon and may affect up to 1 in 100 people*  
dizziness, tiredness, headache or sleep disturbances, including insomnia;

- blurred or double vision;
- indigestion, nausea, vomiting, stomach pain or discomfort, diarrhoea or constipation and wind;
- itching, pimples, hives, rashes, scalp and hair problems (including hair loss);
- bladder problems (painful or more frequent urination, having to pass water at night) and sexual difficulties;
- 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*

- problems with touch including burning or tingling sensations or numbness which may indicate damage to nerves;
- 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 one or more muscles leading to pain or weakness in muscles (myositis or polymyositis or dermatomyositis); pain or weakness in muscles.
- 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.

*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.

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.

**The following side effects have been reported with some statins (medicines of the same type)**

- Nightmares
- Memory loss
- Depression
- Breathing problems 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, 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, 56, 84, 98, 100 and 200 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, 56, 84, 98, 100 and 200 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, 56, 84, 98, 100 and 200 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*

Pharmachemie B.V.

Swensweg 5

2031 GA Haarlem

*Fabrikant*

Pharmachemie BV

Swensweg 5

2031 GA Haarlem

Nederland

TEVA Pharmaceutical Works Private Ltd. Co.  
Pallagi út 13  
4042 Debrecen  
Hongarije

TEVA PHARMA, S.L.U  
Poligone Malpica, Calle C, No4  
50016 Zaragoza  
Spanje

**In het register ingeschreven onder**

RVG 28925, tabletten 10 mg  
RVG 28926, tabletten 20 mg  
RVG 28927, tabletten 40 mg

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

België	Pravastatine TEVA 20 mg, tabletten Pravastatine TEVA 40 mg, tabletten
Denemarken	Pravastatinnatrium Teva 20 mg Tabletter Pravastatinnatrium Teva 40 mg Tabletter
Frankrijk	Pravastatine Teva 10 mg, comprimé Pravastatine Teva 20 mg, comprimé Pravastatine Teva 40 mg, comprimé
Duitsland	Pravastatin-CT 10 mg Tabletten Pravastatin-CT 40 mg Tabletten
Italië	Pravastatina Ratiopharm 10 mg Compresse Pravastatine Ratiopharm 20 mg Compresse Pravastatine Ratiopharm 40 mg Compresse
Nederland	Pravastatinenatrium 10 mg Pharmachemie, tabletten Pravastatinenatrium 20 mg Pharmachemie, tabletten Pravastatinenatrium 40 mg Pharmachemie, tabletten
Noorwegen	Pravastatin Teva 10 mg Tabletter Pravastatin Teva 20 mg Tabletter Pravastatin Teva 40 mg Tabletter
Portugal	Pravastatina Teva 10 mg Comprimidos Pravastatina Teva 20 mg Comprimidos Pravastatina Teva 40 mg Comprimidos
Spanje	Pravastatina Teva 10 mg, Comprimidos EFG Pravastatina Teva 20 mg, Comprimidos EFG Pravastatina Teva 40 mg, Comprimidos EFG
Zweden	Pravastatin Teva 10 mg tabletter Pravastatin Teva 20 mg tabletter Pravastatin Teva 40 mg tabletter

Deze bijsluiter is voor de laatste keer goedgekeurd in maart 2024.