

Package leaflet: Information for the patient

LIPOVAS 20 mg TABLETS

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

1. WHAT LIPOVAS IS AND WHAT IT IS USED FOR

The name of this medicine is Lipovas 20 mg Tablets (called Lipovas in this leaflet). The active ingredient is pravastatin sodium.

Lipovas 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 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 and to lower your risk of dying from these diseases.

- If you have already had a heart attack 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.

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 LIPOVAS

Do not take Lipovas

- if you are allergic to Lipovas 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 section 2. “Pregnancy, breast-feeding and fertility”).
- 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).

Ask your doctor if you are uncertain whether you can take Lipovas.

Warnings and precautions

Talk to **your doctor** or pharmacist before taking Lipovas **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)**
- **a 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 section 2. “Other medicines and Lipovas”)**
- respiratory failure

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, weakness, or tenderness 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.

If you develop breathing problems including persistent cough and/or shortness of breath or fever (symptoms of interstitial lung disease), tell your doctor immediately as your treatment should be discontinued.

If you are uncertain about taking Lipovas, go back to your doctor as soon as possible to discuss your concerns and follow the advice given.

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.

Children

In children before puberty (puberty is the process of physical changes by which a child's body becomes an adult body capable of reproduction); the benefit/risk of treatment should be carefully evaluated by physicians before treatment initiation.

Other medicines and Lipovas:

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.

When combined with this treatment, **the medicines stated below may result in an increased risk of developing muscle problems** (see section 4. "Possible side effects"). It is important that you inform your doctor whether you are already being treated with:

a medicine which lowers the cholesterol level in the blood (fibrates, e.g. gemfibrozil, fenofibrate).

- a medicine which lowers the body's immune defences (cyclosporin).
- a medicine which treats the infections caused by bacteria (an antibiotic such as erythromycin or clarithromycin).
- a medicine for controlling of the uneven beating of your heart called "arrhythmias" (amiodarone)
- another medicine which lowers the level of cholesterol in your blood (nicotinic acid).

Concomitant use of Lipovas and the medicines such as cyclosporin, erythromycin or clarithromycin results in increased pravastatin levels in your blood.

However, the medicine nelfinavir (for AIDS treatment) may decrease the Pravastatin levels in your blood.

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 colestyramine or one hour before you have taken colestipol. This is because the resin can affect the absorption of Lipovas if the two medicines are taken too closely together.

Lipovas with food, drink and alcohol

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, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Pregnancy

Do not take Lipovas during pregnancy. If you discover that you are pregnant, you should inform your doctor immediately.

Breast-feeding

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

Ask your doctor or pharmacist for advice before taking any medicine

Driving and using machines

Lipovas 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.

Lipovas Tablets contain lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. HOW TO TAKE LIPOVAS

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 low fat diet which you should continue over the full treatment period.

Dosage

Adults

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

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

- 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.

Renal and hepatic impairment

If you suffer from kidney or severe liver disease, your doctor may prescribe a lower dose of Lipovas to you.

Older people

No dosage adjustment is required for this group. The same dosage as for adult patients can be used. Your doctor will tell you how much to take.

Other medicines

If you are also taking a medicine which lowers the body's immune system (cyclosporin), 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 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 colestyramine or one hour before you have taken colestipol.

Use in children and adolescents

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 daily for children between 8 and 13 years of age and from 10-40 mg once daily for children between 14 and 18 years.

Lipovas is not recommended for children below 8 years.

Method of administration

Lipovas should be taken once a day, preferably in the evening.

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

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 Lipovas. 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 Lipovas 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 Lipovas:

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 stop taking Lipovas:

It is important that you keep taking Pravastatin for as long as your doctor has told you. If you stop taking Lipovas, your cholesterol or lipid levels may rise again.

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 Lipovas and see a doctor or go to a hospital straight away if:

- you get **sudden severe allergic reactions including swelling of the face, lip, tongue or wind pipe which can cause great difficulty in breathing.** This may mean you are having an allergic reaction to Lipovas.
- 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.**
- you develop a severe skin disease (lupus erythematosus-like syndrome)
- you get severe stomach pain which may reach through to your back (pancreatitis)
- you get liver problems, such as yellowing of the skin or eyes (jaundice/hepatitis)

The side effects listed above are serious but very rare (may affect up to 1 in 10,000 people).

Other side effects

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

- 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

Very rare side effects (**may affect up to 1 in 10,000 people**) include:

- problems with touch including burning or tingling sensations or numbness which may indicate damage to nerves
- 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); pain or weakness in muscles, inflammation of tendons which may be complicated by rupture of tendons

Side effects of unknown frequency

- muscle weakness that is constant

Laboratory test results

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.

Possible side effects 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 or pharmacist. 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 LIPOVAS

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 which is stated on the carton and blister after “Exp.”. 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 Lipovas contains

- The active substance is pravastatin sodium. Each tablet contains 20 mg Pravastatin.
- The other ingredients are anhydrous lactose, sodium stearyl fumarate and yellow iron oxide (E172).

What Lipovas looks like and contents of the pack

Lipovas 20 mg Tablets are yellow to dark yellow, mottled, circular, biconvex tablets marked “P2” on one side and have a breakline on the other side. The tablets can be divided into equal doses.

Lipovas comes in packs of 10, 14, 20, 28, 30, 50, 98 or 100 tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder

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This medicinal product is authorised in the Member States of the EEA under the following names:

Ireland: Lipovas 10/20/40 mg Tablets

Italy: PRAVASTATINA Pensa 20/40 mg compresse

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