

Package leaflet: Information for the patient

Lipaprav 10 mg Film-coated Tablets

Lipaprav 20 mg Film-coated Tablets

Lipaprav 40 mg Film-coated 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 Lipaprav is and what it is used for
2. What you need to know before you take Lipaprav
3. How to take Lipaprav
4. Possible side effects
5. How to store Lipaprav
6. Contents of the pack and other information

1. What Lipaprav is and what it is used for

Lipaprav 10 mg, 20 mg and 40 mg film-coated tablets contain pravastatin, which belongs to a group of medicines called statins. Statins work by reducing high cholesterol levels in the blood. Cholesterol is a fatty substance (lipid) that can cause the narrowing of the heart muscle blood vessels (coronary heart disease).

Lipaprav is used

- to lower a high **cholesterol level** in the blood when there is insufficient response to diet, more exercise, weight reduction etc.
- if you are at **risk of narrowing of the blood vessels in your heart** caused by too much cholesterol in your blood, as a supplement to your diet.
- to reduce the chance of having another heart attack if you have had a heart attack or if you have chest pain attacks (unstable angina pectoris).
- to lower the fatty substances (lipids) in the blood following an **organ transplant**.

2. What you need to know before you take Lipaprav

Do not take Lipaprav

- if you are allergic to pravastatin or any of the other ingredients of this medicine (listed in section 6).
- if you suffer from a **liver disease** in an active stage or if liver function tests keep showing excessive values without any identifiable reason.
- if you are **pregnant** or **breast-feeding**.

Warnings and precautions

Talk to your doctor or pharmacist before taking Lipaprav

- if you suffer from a **kidney disease** or have a history of **liver disease**.
- if you regularly drink large amounts of **alcohol**.
- if you suffer from a low function of your **thyroid gland**.

- 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 Lipapprav can lead to serious muscle problems (rhabdomyolysis).
- if you use **other medication (fibrates)** to lower the fatty substances at the same time.
- if you experienced **muscle problems** during previous treatment medication to lower the fatty substances or if anyone in your family suffers from a hereditary muscle disease.
- if you have severe respiratory failure.

Consult your doctor if this applies to you or has applied to you in the past.

Consult your doctor immediately if, while using Lipapprav, you get unexplained muscle ache, muscle weakness, muscle cramps or muscle tenderness, particularly in combination with tiredness and fever. These complaints may be caused by the use of Lipapprav.

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.

If necessary, your doctor may decide to stop treatment. Lipapprav should not be used if you have muscle disease or if you develop kidney problems which are probably a result of destruction of muscle tissue associated with muscle cramps, fever and red-brown discoloration of the urine (rhabdomyolysis).

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 or fats in your blood, are overweight or have high blood pressure.

Children

Children younger than 8 years should not use this medicine, because safety and efficacy is not proven in this patient group.

Other medicines and Lipapprav

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

If you take Lipapprav together with certain other medicines, the effect either of Lipapprav or of the other medicine or of both may be influenced. Inform your doctor or pharmacist especially if you take or have recently taken any of the following medicines:

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 Lipapprav. Taking Lipapprav with fusidic acid may rarely lead to muscle weakness, tenderness or pain (rhabdomyolysis). See more information regarding rhabdomyolysis in section 4.

- medicines known as fibrates, which decrease fat levels in the blood (e.g. **gemfibrozil** and **fenofibrate**). The accompanying use with pravastatin may result in, sometimes severe, muscle problems.
- **colestyramine** and **colestipol** (medicines used for the treatment of a high cholesterol level). The effect of pravastatin is weakened when taken at the same time as with one of those medicines.
- **nicotinic acid** (another medicine which lowers the level of cholesterol in your blood).
- **ciclosporin** (a medicine used to suppress the immune system). The effect of pravastatin is highly intensified when being used together.
- **erythromycin** and **clarithromycin**. These antibiotics intensify the effect of pravastatin.
- if you are taking a drug used to treat and prevent formation of blood clots called **vitamin K antagonist**, tell your doctor before taking Lipapprav because the use of vitamin K antagonists concomitantly with Lipapprav might increase the results of blood tests used to monitor the treatment with vitamin K antagonists.

Lipaprav with alcohol

It is best not to drink any alcohol until your treatment with Lipaprav has finished.

Pregnancy and breast-feeding

Do **not** use Lipaprav during pregnancy or breast-feeding.

During pregnancy the active substance pravastatin is very likely to harm the unborn baby. During breast-feeding small amounts pass into the mother's milk which is bad for the baby's health. 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. Girls and women of childbearing age should use reliable contraceptives. If, however, you become pregnant during treatment, you should stop using Lipaprav and consult your doctor. Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

Lipaprav does not usually affect the ability to drive and use machines. You may, however, feel **dizzy or your vision** may be affected. In this case make sure that you are fit to drive and operate machinery.

Lipaprav contains lactose

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

3. How to take Lipaprav

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

For lowering an increased cholesterol level in the blood

Lipaprav 10 mg: The recommended dose is 1 - 4 tablets (10 - 40 mg pravastatin) once daily. The maximum daily dosage is 4 tablets (40 mg pravastatin).

Lipaprav 20 mg: The recommended dose is ½ - 2 tablets (10 - 40 mg pravastatin) once daily. The maximum daily dosage is 2 tablets (40 mg pravastatin).

Lipaprav 40 mg: The recommended dose is 1 tablet of Lipaprav 10 mg, 10 mg pravastatin (your doctor will prescribe you this lower strength, if necessary) or ½ - 1 tablet of Lipaprav 40 mg (20 - 40 mg pravastatin) once daily. The maximum daily dosage is 1 tablet of Lipaprav 40 mg (40 mg pravastatin).

To prevent heart attack or stroke

Lipaprav 10 mg: The recommended dose is 4 tablets (40 mg pravastatin) once daily.

Lipaprav 20 mg: The recommended dose is 2 tablets (40 mg pravastatin) once daily.

Lipaprav 40 mg: The recommended dose is 1 tablet (40 mg pravastatin) once daily.

Following a transplant

Lipaprav 10 mg: The recommended dose is 2 tablets (20 mg pravastatin) once daily. The dosage can be increased up to 4 tablets (40 mg pravastatin) once daily.

Lipaprav 20 mg: The recommended dose is 1 tablet (20 mg pravastatin) once daily. The dosage can be increased up to 2 tablets (40 mg pravastatin) once daily.

Lipaprav 40 mg: The recommended dose is ½ tablet (20 mg pravastatin) once daily. The dosage can be increased up to 1 tablet (40 mg pravastatin) once daily.

Use in children and adolescents with hereditarily increased cholesterol in the blood (heterozygous familial hypercholesterolaemia)

Lipaprav 10 mg: The recommended dose is 1 - 2 tablets (10 - 20 mg pravastatin) once daily for children 8 - 13 years of age and 1 - 4 tablets (10 - 40 mg pravastatin) once daily for adolescents 14 - 18 years of age.

Lipaprav 20 mg: The recommended dose is ½ - 1 tablet (10 - 20 mg pravastatin) once daily for children 8 - 13 years of age and ½ - 2 tablets (10 - 40 mg pravastatin) once daily for adolescents 14 - 18 years of age.

Lipaprav 40 mg: The recommended dose is 1 tablet of Lipaprav 10 mg, 10 mg pravastatin (your doctor will prescribe you this lower strength, if necessary) or ½ tablet of Lipaprav 40 mg (20 mg pravastatin) once daily for children 8 - 13 years of age and 1 tablet of Lipaprav 10 mg, 10 mg pravastatin or ½ - 1 tablet of Lipaprav 40 mg (20 - 40 mg pravastatin) once daily for adolescents 14 - 18 years of age.

Dosage adjustment in kidney or liver problems

The recommended initial dose is 1 tablet of Lipaprav 10 mg Film-coated Tablet once daily; the dosage can be adjusted, if necessary.

Use with other medicines

In case of accompanying use of other medicines with the active ingredients **colestyramine** or **colestipol** (medicines used for the treatment of high cholesterol levels), you should take Lipaprav at least one hour before or four hours after these medicines.

If at the same time you use other medicines with the active ingredient **ciclosporin** (a medicine used to suppress the immune system), the initial dosage of Lipaprav is:

Lipaprav 10 mg: 2 tablets (20 mg pravastatin) once daily. This can be increased to up to 4 tablets (40 mg pravastatin).

Lipaprav 20 mg: 1 tablet (20 mg pravastatin) once daily. This can be increased to up to 2 tablets (40 mg pravastatin).

Lipaprav 40 mg: ½ tablet (20 mg pravastatin) once daily. This can be increased to up to 1 tablet (40 mg pravastatin).

Take Lipaprav once daily, preferably in the evening, with or without meals. Swallow the tablets with a sufficient quantity of liquid (e.g. one glass of water).

Follow these instructions unless your doctor gave you different advice. Remember to take your medicine.

The tablet can be divided into equal doses.

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

If you take more Lipaprav than you should

If you have taken too many tablets, or if someone has accidentally swallowed some tablets, contact your doctor or pharmacist immediately.

If you forget to take Lipaprav

If you miss a dose, simply take your normal dose when it is next due. Do **not** take a double dose to make up for a forgotten dose.

If you stop taking Lipaprav

Take Lipaprav as long as your doctor has told you. If you stop taking Lipaprav, your cholesterol levels may increase 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.

Contact your doctor immediately if you develop one of these side effects during the use of Lipaprav:

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

- hypersensitivity reactions:
 - serious allergic reactions with swelling of the face, lips, tongue, wind pipe or other parts of the body which can cause shortness of breath, wheezing or great difficulty in breathing (angioedema, anaphylaxis).
 - Skin rash, possibly with pain in the joints (Lupus erythematosus-like syndrome).
- destruction of muscle fibres (rhabdomyolysis) that may be associated with acute kidney failure (see also section 2. “What you need to know before you take Lipaprav”), inflammation of the muscles/many muscles (myositis/polymyositis). This may cause aching muscles, muscle tenderness or weakness not caused by exercise, decreased urine, dark coloured urine and increased creatinine kinase which can be seen in a blood test. Presence of myoglobin in the urine which can be seen in a urine test (myoglobinuria).
- serious liver problems including yellowish discoloration of the skin and/or eyes (jaundice), tissues and body fluids, liver inflammation (hepatitis), sudden rapid destruction of liver tissue (fulminant hepatic necrosis). This may cause you to feel or be sick, lose appetite, feel generally unwell, fever, itchy skin, dark urine, pale stools
- inflammation of the pancreas. This causes moderate to severe pain in the stomach, which spreads to the back (pancreatitis)

Not known (cannot be estimated from the available data)

- diabetes. This is more likely if you have high levels of sugars or fats in your blood, are overweight or have high blood pressure. You may have excessive thirst, increased appetite with weight loss, feeling tired, drowsy, weak, depressed, irritable and generally unwell, and passing large amounts of urine. Your doctor will monitor you while you are taking this medicine
- breathing problems including persistent cough with shortness of breath and/or fever (interstitial lung disease)
- muscle weakness that is constant (Immune –mediated necrotising myopathy)
- a condition characterised by an inflammation of the muscles and the skin (dermatomyositis).

Other possible side effects include:**Common (may affect up to 1 in 10 people)**

- increased production of liver enzymes which can be seen in a blood test.

Uncommon (may affect up to 1 in 100 people)

- dizziness
- headache
- sleep disturbances, lack of sufficient sleep
- vision disturbance (blurred vision or double vision)
- indigestion (dyspepsia) or heartburn
- abdominal pain
- feeling sick (nausea) or being sick (vomiting)
- constipation
- diarrhoea
- wind
- itching, rash, hives, scalp and hair problems (including hair loss)
- abnormal urination, e.g. pain when passing urine (dysuria), change in frequency or frequent urination at night (nocturia)
- disturbed sexual functions
- tiredness

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

- problems with touch including burning/tingling sensation, numbness or pins and needles (paraesthesia) may occur which may be a sign of damage to the nerve endings (peripheral polyneuropathy)

- tendon problems, sometimes associated with tearing. This may cause muscle pain, swelling, redness and restriction in movement

Not known (cannot be estimated from the available data)

- painful joints (arthralgia)

The following side effects have been seen with other medicines similar to pravastatin and may be seen with this medicine.

Not known (cannot be estimated from the available data)

- depression
- nightmares
- memory loss

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 HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971 FREE Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Lipaprav

Keep this medicine out of the sight and reach of children.

Do not store above 25°C. Store in the original package in order to protect from moisture.

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 Lipaprav contains

The **active substance** is pravastatin sodium.

Lipaprav 10 mg: each tablet contains 10 mg pravastatin sodium.

Lipaprav 20 mg: each tablet contains 20 mg pravastatin sodium.

Lipaprav 40 mg: each tablet contains 40 mg pravastatin sodium.

The **other ingredients** are:

Tablet core: microcrystalline cellulose, croscarmellose sodium, macrogol 8000, copovidone, heavy magnesium carbonate, lactose monohydrate (see section 2 "Lipaprav contains lactose"), magnesium stearate, iron oxide red (E172) (for the 10mg tablets only), iron oxide yellow (E172) (for the 20mg and 40mg tablets only), silica colloidal anhydrous.

Tablet coating: hydroxypropylcellulose, macrogol 400, macrogol 3350, hypromellose.

What Lipaprav looks like and contents of the pack

Lipaprav 10 mg: Pink-peach film-coated tablet with "10" on one side.

Lipaprav 20 mg: Yellow film-coated tablet with "20" on one side.

Lipaprav 40 mg: Yellow film-coated tablet with "40" on one side.

Lipaprav is available in blister packs of 7, 10, 14, 20, 28, 30, 50, 56, 60, 98, 100 and 200 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

McDermott Laboratories Ltd. t/a Gerard Laboratories, 35/36 Baldoyle Industrial Estate, Grange Road,
Dublin 13, Ireland

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