

Lipidil(R)

48 and 145 mg

Fenofibrate

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Lipidil. It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking Lipidil against the benefits this medicine is expected to have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What Lipidil is used for

Lipidil is used to help regulate cholesterol and triglycerides which are fat-like substances in the blood.

Cholesterol is present in many foods and is also made in your body by the liver. If your body does not balance the amount of cholesterol it needs with the amount of cholesterol eaten, then your cholesterol becomes too high.

High cholesterol is more likely to occur with certain diseases or if you have a family history of high cholesterol.

When you have high levels of cholesterol it may 'stick' to the inside of your blood vessels instead of being carried to the parts of the body where it is needed.

Over time, this can form hard areas (called plaque) on the walls of your blood vessels, making it more difficult for the blood to flow. This blocking of your blood vessels can lead to heart disease (such as heart attack and angina), and stroke.

Cholesterol is carried through the body by different proteins, LDL and HDL. LDL cholesterol is the 'bad' cholesterol that can block your blood vessels. HDL cholesterol is the 'good' cholesterol that is thought to remove the 'bad' cholesterol from the blood vessels.

In most patients, Lipidil reduces the bad cholesterol and can actually raise the good cholesterol.

Lipidil does not reduce the cholesterol that comes from fat in food.

Therefore, when you are taking Lipidil, you also need to follow a low fat diet and other measures, such as exercise and weight control.

How Lipidil works

Lipidil works through the activation of a cell nuclear receptor called PPAR alpha, which reduces the amount of triglycerides and bad cholesterol made in the body and increases the good cholesterol.

Lipidil belongs to a group of medicines known as fibric acid derivatives.

Your doctor will have explained why you are being treated with Lipidil. Follow all directions given to you by your doctor carefully. They may

differ from the information contained in this leaflet.

There is no evidence that Lipidil is addictive.

This medicine is available only with a doctor's prescription.

Before you take Lipidil

When you must not take it

Do not take Lipidil if:

1. you have an allergy to:

- * Lipidil or any of the ingredients listed at the end of this leaflet in particular lactose or lecithin
- * Gemfibrozil

Symptoms of an allergic reaction include:

- * severe skin rash or hives
- * severe skin disease

2. you are pregnant, or intend to become pregnant.

Lipidil may affect your developing baby if you take it during pregnancy.

3. you are breast-feeding or intend to breast-feed.

Lipidil passes into breast milk and may affect your baby.

4. you have liver disease

5. you have severe kidney disease

6. you have gallbladder disease

7. you have had muscle pain, tenderness or weakness from other medicines used to treat high cholesterol or triglycerides

Do not take/use Lipidil if the packaging is torn or shows signs of tampering.

Do not take/use Lipidil if the expiry date (EXP) printed on the pack has passed.

If you take this medicine after the expiry date has passed, it may not work (as well).

If you are not sure whether you should start taking/using Lipidil, contact your doctor.

Do not give Lipidil to a child under 18 years.

The safety and effectiveness of Lipidil in children have not been established.

Before you start to take it

Tell your doctor if:

1. **you have any allergies to any other medicines or any other substances, such as food, preservatives or dyes.**

2. **you are pregnant or intend to become pregnant**

Lipidil should not be used during pregnancy or while breast-feeding.

3. **you are breast-feeding or intend to breast-feed**

Your doctor will discuss the risks and benefits of using Lipidil when breast-feeding.

4. **you have or have had any other medical conditions, including:**

- * kidney problems
- * muscular aching, tenderness or weakness not caused by exercise

If you have not told your doctor about any of the above, tell them before you take any Lipidil.

Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with Lipidil. These include:

- * oral anti-coagulants (medicines used to prevent blood clots)
- * other cholesterol regulating medicines including fibrates
- * cyclosporin (a medicine which suppresses the immune system)

These medicines may be affected by Lipidil, or may affect how well it works. You may need different amounts of your medicine, or you may need to take different medicines. Your doctor will advise you.

Your doctor or pharmacist may have more information on medicines to be careful with or to avoid while taking Lipidil.

How to take Lipidil

How much to take

Follow all directions given to you by your doctor and pharmacist carefully.

These directions may differ from the information contained in this leaflet.

The initial recommended dose is 145 mg daily, taken as 1 x 145 mg tablet.

If you do not understand the instructions on the box, ask your doctor or pharmacist for help.

How to take it

Swallow Lipidil whole with a glass of water.

When to take it

Lipidil can be taken at any time of the day, with or without food. Any dietary measures started before treatment with Lipidil should be continued.

Take Lipidil at about the same time each day.

Taking tablets at the same time each day will have the best effect. It will

also help you remember when to take the tablets.

How long to take it

Lipidil helps to regulate your levels of cholesterol (both LDL and HDL) and triglycerides. It does not cure your condition. Therefore you must continue to take it as directed by your doctor if you expect to keep your levels controlled. You may have to take this kind of medicine for the rest of your life. If you stop taking Lipidil, your levels may become abnormal again.

If you forget to take it

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to. Otherwise, take it as soon as you remember, and then go back to taking your tablet as you would normally.

If you are not sure whether to skip the dose, talk to your doctor or pharmacist.

Do not take a double dose to make up for the dose that you missed.

If you have trouble remembering to take your tablet, ask your pharmacist for some hints.

If you take too much (overdose)

Immediately telephone your doctor or Poisons Information Centre (telephone 13 11 26), or go to casualty at your nearest hospital, if you think that you or anyone else may have taken too much Lipidil. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention. Keep telephone numbers of these places handy.

While you are using Lipidil

Things you must do

Have your blood fats checked when requested by your doctor to make sure Lipidil is working.

If you become pregnant while you are taking Lipidil stop taking it and contact your doctor immediately.

If you are about to be started on any new medicine tell your doctor and pharmacist that you are taking Lipidil.

Things you must not do

Do not give Lipidil to anyone else, even if they have the same condition as you.

Do not use Lipidil to treat any other complaints unless your doctor tells you to.

Things to be careful of

Avoid drinking large quantities of alcohol.

Drinking large quantities of alcohol may increase your chance of Lipidil causing liver problems.

Be careful driving or operating machinery until you know how Lipidil affects you.

Lipidil generally does not cause any problems with your ability to drive a car or operate machinery. However, as with many other medicines, Lipidil may cause dizziness in some people.

Changes to lifestyle that may help reduce the chance of coronary heart disease

Lowering high cholesterol can help reduce your chances of having Coronary Heart Disease (CHD). However, your chances of having CHD may be increased by several other factors including high blood pressure, cigarette smoking, diabetes,

excess weight, family history of CHD, being a male and being a woman who has reached menopause.

Some self-help measures suggested below may help your condition and help reduce your chances of having CHD. Talk to your doctor, pharmacist, or dietician about these measures and for more information.

* **Diet**

- continue the low fat diet recommended by your doctor, dietician or pharmacist.

* **Weight**

- your doctor may advise you to lose weight if you are overweight.

* **Exercise**

- make exercise a part of your routine - walking is good. Ask your doctor for advice before starting exercise.

* **Smoking**

- your doctor will advise you to stop smoking.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Lipidil.

Lipidil helps most people with cholesterol problems, but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor if you notice any of the following and they worry you:

- * Stomach pain or discomfort
- * Back pain
- * Headache
- * Unusual tiredness or weakness
- * Diarrhea or constipation
- * Nausea

- * Skin reactions, photosensitivity reactions

These side effects are usually mild.

If you notice any of the following happen, stop taking Lipidil and tell your doctor immediately or go to casualty at your nearest hospital:

- * Difficulty in breathing
- * Chest pain
- * Temporary paralysis of the muscles
- * Yellowing of the skin and eyes and dark coloured urine

These are very serious side effects. You may need urgent medical attention. These side effects are rare.

Other side effects not listed above may also occur in some patients. Tell your doctor if you notice anything else that is making you feel unwell.

Ask your doctor or pharmacist if you don't understand anything in this list.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

After using Lipidil

Storage

Keep your tablets in the blister pack until it is time to take them.

If you take the tablets out of the blister pack they may not keep well.

Keep Lipidil in a cool dry place where the temperature stays below 30 degrees C. Do not store it or any other medicine in the bathroom or near a sink. Do not leave it in the car or on window sills.

Heat and dampness can destroy some medicines.

Keep it where young children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store

medicines.

Disposal

If your doctor tells you to stop taking the tablets or the tablets have passed their expiry date, ask your pharmacist what to do with any tablets that are left over.

Product Description

What it looks like

- * 48 mg tablet: yellow, oblong, film-coated tablet engraved "48" on one side and "Fournier logo" on the reverse.
Packs of 60 tablets in a blister pack.
- * 145 mg tablet: white, oblong, film-coated tablet engraved "145" on one side and "Fournier logo" on the reverse.
Packs of 30 tablets and 10 (Physican's Sample) tablets in a blister pack.

Ingredients

Active Ingredient.

Fenofibrate, 48 mg per tablet.

Fenofibrate, 145 mg per tablet.

Excipient Ingredients

- * sucrose
- * hypromellose
- * sodium lauryl sulfate
- * lactose
- * crospovidone
- * cellulose microcrystalline
- * silica colloidal anhydrous
- * docusate sodium
- * magnesium stearate

Tablet coating:

Lipidil 48 mg

- * polyvinyl alcohol
- * titanium dioxide
- * purified talc
- * lecithin
- * xanthan gum

- * indigo carmine
- * quinoline yellow
- * sunset yellow FCF.

Lipidil 145 mg

- * polyvinyl alcohol
- * titanium dioxide
- * purified talc
- * lecithin
- * xanthan gum.

Supplier

Laboratoires Fournier Australia
Level 1, Bldg 2, 20 Bridge Street
Pymble, NSW 2073

Lipidil 48 mg: AUST R 118642

Lipidil 145 mg: AUST R 118634

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