

Consumer Medicine Information

What is in this leaflet

The information in this leaflet will answer some of the questions you may have about LIPOSTAT. This leaflet does not tell you everything about LIPOSTAT. This leaflet is no substitute for talking with your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risk of you taking LIPOSTAT against the benefits they expect it will have for you.

Ask your doctor or pharmacist if you have any concerns about taking this medicine.

Keep this leaflet with the medicine.

You may need to read it again.

What is LIPOSTAT used for?

LIPOSTAT tablets contain pravastatin sodium, a drug that reduces the level of cholesterol in your blood and helps to protect you in other ways from heart attack or stroke. It is more effective if it is taken with a diet low in fat.

LIPOSTAT is used to treat people who have had a heart attack or an episode of unstable angina, or who have high blood cholesterol levels. In these people this medicine can reduce the risk of further heart disease, reduce the possibility of needing a bypass operation, or reduce the risk of having a stroke.

LIPOSTAT lowers high blood cholesterol levels. It is also used if your cholesterol levels are normal if you have had a heart attack or an episode of unstable angina.

LIPOSTAT is used to treat heterozygous familial hypercholesterolaemia in children and adolescent patients aged 8 years and older as an adjunct to diet and lifestyle changes.

If you have had a heart attack, an episode of unstable angina or you have too much cholesterol in your blood, then you have an increased risk of a blood clot forming in your blood vessels and causing a blockage. Blood vessels that become blocked in this way can lead to further heart disease, angina or stroke.

LIPOSTAT may be used to lower lipids in heart or kidney transplant patients, who are also being given immunosuppressive medicine.

It is used to treat long-term (chronic) conditions so it is important that you take your medicine every day.

LIPOSTAT is not addictive or habit forming. The medicine is only available upon prescription from your doctor.

Before you take it

When you must not take it

You should not take LIPOSTAT if you

- have ever had an allergic reaction to pravastatin sodium or any other ingredient listed at the end of this leaflet
- have ever had liver disease
- have had muscle pain from any other medicine used to treat high cholesterol

Do not take this medicine after the expiry (exp) printed on the pack.

If you take this medicine after the expiry, it may not work as well.

Do not take this medicine if the blisters show signs of tampering.

Talk to you doctor if you are not sure whether you should start taking this medicine.

Before you start to take it

Before you take LIPOSTAT for the first time you should tell your doctor if you

- are taking other medicines or treatment
- drink alcohol regularly
- have ever had liver problems
- have a problem with your kidneys
- may become pregnant
- are breastfeeding
- suffer from hormonal disorders
- suffer from central nervous system vascular lesions
- suffer from allergies
- suffer from homozygous familial hypercholesterolaemia, (a doctor will have told you this)
- have increased triglycerides in your blood (a doctor will have told you this also)
- suffer from muscle disease (including pain, tenderness or weakness).

Taking other medicines

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

It is especially important that you tell your doctor if you are taking any of the following:

- any other medicine to lower cholesterol
- cyclosporin
- ketoconazole
- spironolactone
- cimetidine
- gemfibrozil
- cholestyramine and colestipol
- antacids
- Macrolides
- Propanol
- Bile acid sequestrants
- Digoxin
- Warfarin or other coumarin anticoagulants

Please discuss any of these with your doctor if you need to take any of them.

LIPOSTAT generally does not interfere with your ability to drive or operate machinery. However some people may experience dizziness, so you should be sure how you react to LIPOSTAT before you drive a car, or operate machinery.

How to take it

Follow all directions given to you by your doctor carefully.

They may differ from the information contained in this leaflet.

Ask your doctor or pharmacist for help if you do not understand the instructions on the pack.

How much to take

Your doctor will decide on the correct dose of LIPOSTAT, this will depend on many factors including your cholesterol level. The dose for lowering cholesterol is 10 – 80mg, and is 40mg for reducing the possibility of a stroke or heart attack.

The recommended dose is 20 mg once daily for children 8 – 13 years of age and 40 mg once daily in adolescents 14 – 18 years of age, with heterozygous familial hypercholesterolaemia.

How to take it

Swallow the tablet whole with a glass of water.

When to take it

Take LIPOSTAT **once a day** in the evening before bed-time.

For best results, take LIPOSTAT on an empty stomach (ie. two or more hours after your last meal).

Take LIPOSTAT at about the same time each day. Taking it at the same time each day will have the best effect and will also help you remember when to take it.

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.

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

This may increase the risk of you getting unwanted side effects.

Ask your doctor or pharmacist if you are not sure what to do.

If you take too much (overdose)

Immediately telephone your doctor or Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at the nearest hospital if you think that you, or anyone else may have taken too much LIPOSTAT. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

While you are taking it

Things you must do

Immediately stop taking LIPOSTAT at the first sign of unexplained muscle pain, tenderness or weakness. Do this even if your symptoms have not been relieved.

Tell your doctor, dentists, and pharmacists who are treating you that you are taking this medicine, especially if you are being started on any new medicines.

Tell your doctor, surgeon, or anaesthetist that you are taking LIPOSTAT if you are about to undergo surgery or an operation.

Tell your doctor immediately if you become pregnant while taking this medicine.

Side effects

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

The most common side effects of LIPOSTAT are:

- upset stomach
- nausea
- diarrhoea
- wind
- constipation
- headache
- dizziness.

You may also experience-

- sleep disturbances including insomnia and nightmares
- depression
- sexual dysfunction
- exceptional cases of interstitial lung disease, especially with long term therapy.

Tell your doctor as soon as possible if you have any of these side effects or any other problem while taking LIPOSTAT.

Your doctor may arrange blood tests.

You must tell your doctor immediately, or go to the hospital, if you suffer any of the following:

- unexplained muscle pain
- tenderness or weakness.

It is also possible to suffer from an allergic reaction to LIPOSTAT.

Tell your doctor if you develop a skin rash or itchiness, fever, joint pain or shortness of breath.

In few cases, statins have been reported to induce de novo or aggravate pre-existing myasthenia gravis or ocular myasthenia.

After taking it

Storage

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

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

Keep the tablets in a cool dry place where the temperature stays below 25°C.

Do not store LIPOSTAT or any other medicine in the bathroom or near a sink.

Do not leave it on the window sill of in the car.

Heat and dampness will destroy some medicines.

Keep it in a place children cannot reach.

A locked cupboard at least one and a half meters above the ground is a good place to keep medicines.

Disposal

If your doctor tells you to stop taking LIPOSTAT or the expiry date is passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

LIPOSTAT 10mg tablet - engraved '10'
AUST R 118589

LIPOSTAT 20mg tablet - engraved '20'
AUST R 118590

LIPOSTAT 40mg tablet - engraved '40'
AUST R 118591

LIPOSTAT 80mg tablet – engraved '80'
AUST R 118592

LIPOSTAT tablets are yellow capsule shaped tablets supplied in blister packs containing 30 tablets per pack.

Active ingredients

LIPOSTAT 10mg tablets - 10mg pravastatin sodium

LIPOSTAT 20mg tablets - 20mg pravastatin sodium

LIPOSTAT 40mg tablets - 40mg pravastatin sodium

LIPOSTAT 80mg tablets - 80mg pravastatin sodium

Inactive ingredients

LIPOSTAT tablets also contain

- lactose monohydrate
- povidone
- microcrystalline cellulose
- croscarmellose sodium
- magnesium stearate
- magnesium oxide
- iron oxide-yellow

Contains sugars as lactose monohydrate.

Supplier

Arrow Pharma Pty Ltd
15 – 17 Chapel Street
Cremorne Victoria 3121

This leaflet was revised in October 2023.