

CHOLSTAT®

pravastatin sodium

CONSUMER MEDICINE INFORMATION

What is in this leaflet

This leaflet answers some common questions about CHOLSTAT.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

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

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

Keep this leaflet with your medicine.

You may need to read it again.

What CHOLSTAT is used for

CHOLSTAT is used to:

- lower high blood cholesterol levels (doctors call this hypercholesterolaemia).
- treat people who have had a heart attack or an episode of unstable angina pectoris (chest pain), even when their cholesterol levels are normal.
- lower cholesterol in heart or kidney transplant patients, who are also being given immunosuppressive medicine.
- reduce the risk of further heart disease
- reduce the risk of having a stroke
- treat heterozygous familial hypercholesterolaemia in children and adolescent patients aged 8 years and older as an added measure to diet and lifestyle changes.

There are different types of cholesterol, called 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.

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 plaques] 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.

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.

CHOLSTAT 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.

Ask your doctor if you have any questions about why CHOLSTAT has been prescribed for you.

Your doctor may have prescribed CHOLSTAT for another reason.

CHOLSTAT is available only with a doctor's prescription.

There is no evidence that CHOLSTAT is addictive.

Before you take CHOLSTAT

When you must not take it

Do not take CHOLSTAT if you are allergic to medicines containing pravastatin sodium, any other medicine used to

reduce the level of cholesterol in your blood or any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include skin rash, itching or hives; swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing, wheezing or shortness of breath.

Do not take CHOLSTAT if you:

- have ever had liver problems
- have had muscle pains caused by any other medicine used to treat high cholesterol or triglycerides (fats).

Do not take CHOLSTAT if you are pregnant or planning to become pregnant.

CHOLSTAT can harm your developing baby if you take it during pregnancy. Women who are able to conceive, should not take CHOLSTAT unless using effective contraception (e.g., the birth control pill).

Do not take CHOLSTAT if you are breastfeeding.

CHOLSTAT passes into breast milk and can harm your baby.

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

If you take the tablets after the expiry date, they may not work as well.

Do not take CHOLSTAT if the packaging shows signs of tampering or the tablets do not look quite right.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it

Tell your doctor if you are allergic to any other medicines, foods, dyes or preservatives.

Let your doctor know if you are drinking alcohol while taking CHOLSTAT.

Tell your doctor if you have, or have had, any medical conditions, especially the following:

- liver problems
- kidney problems
- diabetes
- under-active thyroid
- suffer from central nervous system vascular lesions
- hormonal disorders
- increased triglycerides in blood
- homozygous familial hypercholesterolaemia
- increased triglycerides in your blood

- suffer from muscle disease (including pain, tenderness or weakness)
- are or may become pregnant
- are breastfeeding

Your doctor may want to take special care if you have or had any of these conditions.

Tell your doctor if you drink alcohol regularly.

Tell your doctor if you plan to have surgery.

If you have not told your doctor about any of the above, tell them before you start taking CHOLSTAT.

Taking other medicines

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

Some medicines may be affected by CHOLSTAT, or may affect how well it works. These include:

- any other medicine to lower cholesterol
- gemfibrozil and fenofibrate
- colestyramine and colestipol
- ciclosporin

- colchicine
- ketoconazole
- spironolactone
- cimetidine
- nicotinic acid
- erythromycin or clarithromycin
- antacids
- fusidic acid
- propranolol
- rifampicin
- digoxin
- warfarin or another coumarin anticoagulant.

Your doctor can tell you what to do if you are taking any of these medicines.

If you are not sure whether you are taking any of these medicines, check with your doctor or pharmacist.

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

How to take CHOLSTAT

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

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the pack, ask your doctor or pharmacist.

How to take it

Swallow the tablets with a glass of water.

CHOLSTAT tablets should not be divided.

How much to take

The usual starting dose for lowering cholesterol is 10 mg to 20 mg at night, and varied ultimately between 10 mg to 80 mg once a day.

The dose for reducing the possibility of a stroke or heart attack is 40 mg per day.

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.

However, the dose varies from patient to patient. Also, people over 65 may require a lower than usual dose. Therefore, your doctor will decide on the right dose for you after taking into

consideration a number of factors including your cholesterol level and any other medicines that you are taking.

When to take it

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

For the best result, take CHOLSTAT on an empty stomach (e.g., 3 hours after your dinner).

Take your medicine at about the same time each day.

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

How long to take it for

Keep taking CHOLSTAT for as long as your doctor recommends.

To properly control your condition, take CHOLSTAT every day. Treatment with CHOLSTAT is usually long term, even lifelong.

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 the missed dose as soon as you remember, and then go back to taking your tablets as you would normally.

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

If you are not sure what to do or have any questions, ask your doctor or pharmacist.

If you take too much (overdose)

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

You may need urgent medical attention.

While you are taking CHOLSTAT

Things you must do

Before starting any new medicine, tell your doctor or pharmacist that you are taking CHOLSTAT.

Tell all the doctors, dentists and pharmacists who are treating you that you are taking CHOLSTAT.

Use effective contraception (e.g., birth control pill) while you are taking CHOLSTAT.

If you become pregnant while taking CHOLSTAT, tell your doctor immediately.

If you plan to have surgery, including dental surgery, tell your doctor or dentist that you are taking CHOLSTAT.

If you notice that you are getting muscle pain, tenderness or weakness for no reason, tell your doctor as soon as you can.

If you have to have any blood tests tell your doctor that you are taking CHOLSTAT.

CHOLSTAT may affect the results of some tests.

Visit your doctor regularly so they can check on your progress.

Your doctor may want to do some blood tests to check your liver.

Things you must not do

Do not stop taking CHOLSTAT, without checking with your doctor.

Do not use CHOLSTAT to treat any other conditions unless your doctor tells you to.

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

Things to be careful of

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

CHOLSTAT generally does not interfere with your ability to drive or operate machinery. However some people do experience dizziness. If this does occur to you, do not drive, operate machinery or do anything else that could be dangerous.

Side effects

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

Like all other medicines, CHOLSTAT may have unwanted side effects in some people. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

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

Tell your doctor immediately or go to Accident and Emergency at the nearest hospital if you notice any of the following:

- skin rash, itching or hives
- swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing, wheezing or shortness of breath.

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are very rare.

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

- unexplained muscle pain, cramping tenderness and/or weakness (including eye and facial muscle)
- joint pain

The above list includes serious side effects which may require medical attention. Serious side effects are rare.

It is also possible to suffer from an allergic reaction to CHOLSTAT, so tell your doctor if you develop a skin rash or itchiness, fever, joint pain or shortness of breath.

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

- nausea, vomiting
- upset stomach, wind, constipation, diarrhoea.
- headache, dizziness
- vision disturbance, ringing in the ears
- nervousness, sleep disturbance
- tiredness

- passing urine too often.

The above list includes the more common side effects of your medicine. They are usually mild and short-lived.

Tell your doctor if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some patients. Some changes can only be found when your doctor does tests from time to time to check your progress.

After taking CHOLSTAT

Storage

Keep CHOLSTAT where children cannot reach it.

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

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

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

Do not leave CHOLSTAT in the car or on window sills.

Heat and dampness can destroy some medicines.

Disposal

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

Product description

What it looks like

CHOLSTAT comes in 3 strengths of tablets:

- CHOLSTAT 10 - white to off-white, capsule shaped, biconvex tablets with "G | G" on one side and "PR | 10" on the other side
- CHOLSTAT 20 - white to off-white, capsule shaped, biconvex tablets with "G | G" on one side and "PR | 20" on the other side
- CHOLSTAT 40 - white to off-white, capsule shaped, biconvex tablets with "G" on one side and "PR 40" on the other side.

Each pack contains 30 tablets.

Ingredients

The active ingredient in CHOLSTAT is pravastatin sodium.

Each CHOLSTAT 10 tablet contains 10 mg of pravastatin sodium.

Each CHOLSTAT 20 tablet contains 20 mg of pravastatin sodium.

Each CHOLSTAT 40 tablet contains 40 mg of pravastatin sodium.

The tablets also contain:

- aluminium magnesium silicate
- croscarmellose sodium
- povidone
- microcrystalline cellulose
- purified talc
- lactose monohydrate
- magnesium stearate.

CHOLSTAT contains soya bean products and sugars as lactose.

Manufacturer/Supplier

CHOLSTAT is supplied by:

Alphapharm Pty Ltd trading as Viatris

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

www.viatris.com.au

Phone: 1800 274 276

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