

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about taking this medicine, speak to your doctor or pharmacist.

1. Why am I taking CHOLSTAT?

CHOLSTAT contains the active ingredient pravastatin sodium. CHOLSTAT is used to lower cholesterol levels in your blood and reduce the risk of further heart disease or having a heart attack or stroke. It is more effective if it is taken with a diet low in fat.

For more information, see Section [1. Why am I taking CHOLSTAT?](#) in the full CMI.

2. What should I know before I take CHOLSTAT?

Do not take if you have ever had an allergic reaction to pravastatin sodium or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I take CHOLSTAT?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with CHOLSTAT and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I take CHOLSTAT?

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

More instructions can be found in Section [4. How do I take CHOLSTAT?](#) in the full CMI.

5. What should I know while taking CHOLSTAT?

| | |
|------------------------------------|--|
| Things you should do | <ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are taking CHOLSTAT.• Use effective contraception (e.g. birth control pill) while you take CHOLSTAT.• If you notice that you are getting muscle pain, tenderness or weakness for no reason, tell your doctor as soon as you can. |
| Things you should not do | <ul style="list-style-type: none">• Do not stop taking this medicine suddenly without checking with your doctor.• Do not take CHOLSTAT to treat any other conditions or give CHOLSTAT to anyone else. |
| Driving or using machines | <ul style="list-style-type: none">• 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. |
| Drinking alcohol | <ul style="list-style-type: none">• Tell your doctor if you drink alcohol. |
| Looking after your medicine | <ul style="list-style-type: none">• Keep your tablets in a cool dry place where the temperature stays below 25°C, away from moisture, heat and sunlight. |

For more information, see Section [5. What should I know while taking CHOLSTAT?](#) in the full CMI.

6. Are there any side effects?

Common side effects include: headache, dizziness, nausea, vomiting, upset stomach, wind, constipation, diarrhoea, blurred or double vision, ringing in the ears, nervousness, sleep disturbance, tiredness, scalp and hair problems and passing urine too often. Serious side effects include: skin rash, itching or hives, symptoms of an allergic reaction including swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing, wheezing or shortness of breath, unexplained muscle pain, cramping tenderness and/or weakness (including eye and facial muscle) and joint pain.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

CHOLSTAT[®]

Active ingredient: *pravastatin sodium*

Consumer Medicine Information (CMI)

This leaflet provides important information about taking CHOLSTAT. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about taking CHOLSTAT.**

Where to find information in this leaflet:

- [1. Why am I taking CHOLSTAT?](#)
- [2. What should I know before I take CHOLSTAT?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I take CHOLSTAT?](#)
- [5. What should I know while taking CHOLSTAT?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I taking CHOLSTAT?

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

CHOLSTAT is used to:

- lower high blood cholesterol levels (known as 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.

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.

There is no evidence that CHOLSTAT is addictive.

2. What should I know before I take CHOLSTAT?

Warnings

Do not take CHOLSTAT if:

- you are allergic to 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.

Always check the ingredients to make sure you can take this medicine.

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

Do not take CHOLSTAT if the expiry date (EXP.) printed on the pack has passed or if the packaging shows signs of tampering or the tablets do not look quite right.

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

Check with your doctor if you:

- are allergic to any other medicines, foods, dyes or preservatives.
- are drinking alcohol while taking CHOLSTAT.
- have or have had any medical conditions, especially the following:
 - liver problems
 - kidney problems
 - increased triglycerides in the blood or diabetes
 - under-active thyroid

- o suffer from central nervous system vascular lesions
 - o hormonal disorders
 - o homozygous familial hypercholesterolaemia
 - o suffer from muscle disease (including pain, tenderness or weakness)
- take any medicines for any other condition.

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

Tell your doctor if you plan to have surgery.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

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

Pregnancy and breastfeeding

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.

3. What if I am taking other medicines?

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

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

- any other medicines which are used to lower cholesterol, including bile acid sequestrants
- fibrates such as gemfibrozil and fenofibrate
- colestyramine and colestipol
- ciclosporin
- colchicine
- ketoconazole
- spironolactone
- cimetidine
- nicotinic acid
- macrolides such as erythromycin, clarithromycin and roxithromycin
- antacids
- lenalidomide
- fusidic acid
- propranolol
- rifampicin
- digoxin
- warfarin or other coumarin anticoagulants.

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

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect CHOLSTAT.

4. How do I 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 CHOLSTAT

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 to 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 CHOLSTAT

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 CHOLSTAT

If you think that you have taken too much CHOLSTAT, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (Australia telephone 13 11 26) for advice, or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while taking CHOLSTAT?

Things you should 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.
- Statins have been reported to induce de novo or aggravate pre-existing myasthenia gravis or ocular myasthenia.

Call your doctor straight away if you experience these symptoms.

- 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 should not do

- Do not stop taking this medicine suddenly without checking with your doctor.
- Do not take 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.

Driving or using machines

Be careful before you drive or use any machines or tools 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.

Drinking alcohol

Tell your doctor if you drink alcohol.

Looking after your medicine

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

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

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.

Getting rid of any unwanted medicine

If you no longer need to take this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not take this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about 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.

Less serious side effects

| Less serious side effects | What to do |
|---|--|
| Nervous System <ul style="list-style-type: none">• headache, dizziness• tiredness• nervousness, sleep disturbance Special Senses <ul style="list-style-type: none">• blurred or double vision• ringing in the ears. Gastrointestinal <ul style="list-style-type: none">• nausea, vomiting | Speak to your doctor if you have any of these less serious side effects and they worry you. Your doctor may wish to |

| Less serious side effects | What to do |
|---|--|
| <ul style="list-style-type: none"> indigestion, upset stomach, wind, constipation, diarrhoea. <p>Skin and Hair</p> <ul style="list-style-type: none"> scalp and hair problems (including hair loss) pimples <p>Urinary</p> <ul style="list-style-type: none"> bladder problems (painful urination or passing urine more often). <p>Genital</p> <ul style="list-style-type: none"> sexual dysfunction. | <p>arrange blood tests for you.</p> |

Serious side effects

| Serious side effects | What to do |
|--|--|
| <ul style="list-style-type: none"> symptoms of an allergic reaction including 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. unexplained muscle pain, muscle rupture, cramping tenderness and/or weakness (including eye and facial muscle) joint pain | <p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p> |

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

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

What CHOLSTAT contains

| | |
|--|---|
| Active ingredient (main ingredient) | pravastatin sodium |
| Other ingredients | aluminium magnesium silicate croscarmellose sodium |

| | |
|-------------------------------|---|
| (inactive ingredients) | povidone microcrystalline cellulose purified talc lactose monohydrate magnesium stearate. |
| Potential allergens | contains soya bean products and sugars as lactose |

Do not take this medicine if you are allergic to any of these ingredients.

What CHOLSTAT looks like

CHOLSTAT 10 is a white to off-white, capsule shaped, biconvex tablet with "G | G" on one side and "PR | 10" on the other side (AUST R 98486).

CHOLSTAT 20 is a white to off-white, capsule shaped, biconvex tablet with "G | G" on one side and "PR | 20" on the other side (AUST R 98488).

CHOLSTAT 40 is a white to off-white, capsule shaped, biconvex tablet with "G" on one side and "PR 40" on the other side (AUST R 98489).

Who distributes CHOLSTAT

Alphapharm Pty Ltd trading as Viatrix

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

www.viatrix.com.au

Phone: 1800 274 276

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