

CHOLSTAT®

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 helps to protect you in other ways 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?

- CHOLSTAT should only be taken as directed by your doctor.
- Your doctor will decide on the dose, this will depend on many factors including your cholesterol level.

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">• Tell your doctor, dentist or pharmacist you visit that you are taking CHOLSTAT.• Call your doctor straight away if you suffer from an allergic reaction to PRAVACHOL, tell your
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	<p>doctor if you develop a skin rash or itchiness, fever, joint pain or shortness of breath.</p> <ul style="list-style-type: none"> • Call your doctor straight way if you have or have had myasthenia (a disease with general muscle weakness including in some cases muscles used when breathing), or ocular myasthenia (a disease causing eye muscle weakness) as statins may sometimes aggravate the condition or lead to the occurrence of myasthenia.
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 before you drive or use any

	<p>machines or tools until you know how CHOLSTAT affects you.</p> <ul style="list-style-type: none"> • CHOLSTAT may cause dizziness in some people. It 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.

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

6. Are there any side effects?

There are a number of side effects associated with PRAVACHOL. It is important to be aware of them so that you can identify any symptoms if they occur. 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.

It is not addictive or habit forming.

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.
- you have ever had liver problems.

- you have had muscle pains caused by any other medicines used to treat high cholesterol or triglycerides (fats).
- you are or may become pregnant.
- you are breastfeeding.

Check with your doctor if you:

- are allergic to any other medicines, foods, dyes or preservatives.
- are drinking alcohol regularly.
- have or have had any medical conditions, especially the following:
 - liver problems
 - kidney problems
 - increased triglycerides in the blood or diabetes
 - under-active thyroid
 - suffer from central nervous system vascular lesions
 - hormonal disorders
 - homozygous familial hypercholesterolaemia
 - suffer from muscle disease (including pain, tenderness or weakness)
- take any medicines for any other condition.

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?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or plan to become pregnant.

Talk to your doctor if you are breastfeeding or plan to breastfeed.

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 interfere with CHOLSTAT and affect how well it works. These include:

- any other medicines to lower cholesterol
- 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.

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?

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.

Follow the instructions provided and use CHOLSTAT until your doctor tells you to stop.

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.
- Swallow the tablets with a glass of water.
- CHOLSTAT tablets should not be divided.

If you forget to take CHOLSTAT

CHOLSTAT should be taken regularly at the same time each day. If you forget to take a dose of CHOLSTAT, take the next dose normally at your usual time.

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 dose you missed.

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

Call your doctor straight away if you:

- suffer from an allergic reaction to PRAVACHOL, tell your doctor if you develop a skin rash or itchiness, fever, joint pain or shortness of breath.
- have or have had myasthenia (a disease with general muscle weakness including in some cases muscles used when breathing), or ocular myasthenia (a disease causing eye muscle weakness).
- become pregnant.
- plan to have surgery, including dental surgery.
- notice that you are getting muscle pain, tenderness or weakness for no reason.
- have to have any blood tests.

Tell all the doctors, dentists or pharmacists you visit that that you are taking CHOLSTAT.

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 have.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how CHOLSTAT affects you.

CHOLSTAT may cause dizziness and visual disturbances in some people. It generally does not interfere with your ability to drive or operate machinery.

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.

When to discard your medicine

The expiry date is printed on the carton. Do not take it after the expiry date or if the tablets have changed in appearance colour or taste.

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.

Less serious side effects

Less serious side effects	What to do
<p>Nervous System</p> <ul style="list-style-type: none"> • headache • dizziness • tiredness • nervousness • sleep disturbance including insomnia <p>Special Senses</p> <ul style="list-style-type: none"> • blurred or double vision • ringing in the ears. <p>Gastrointestinal</p> <ul style="list-style-type: none"> • nausea • vomiting • indigestion • upset stomach • wind • constipation • diarrhoea. <p>Skin and Hair</p> <ul style="list-style-type: none"> • itching • rashes • scalp and hair problems (including hair loss) 	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p> <p>Your doctor may wish to arrange blood tests for you.</p>

Less serious side effects	What to do
<ul style="list-style-type: none"> • 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. 	

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 • muscle cramps • tenderness and/or weakness (including eye and facial muscle) 	<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>

Serious side effects	What to do
<ul style="list-style-type: none"> • joint pain 	

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
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Other ingredients (inactive ingredients)	aluminium magnesium silicate croscarmellose sodium 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 Viatris

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

www.viatris.com.au

Phone: 1800 274 276

This leaflet was prepared in November 2025.

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