

Praluent[®]

Consumer Medicine Information (CMI) summary

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

1. Why am I using Praluent?

Praluent contains the active ingredient alirocumab. Praluent is used to treat high levels of cholesterol in the blood.

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

2. What should I know before I use Praluent?

Do not use if you have ever had an allergic reaction to Praluent 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, or are pregnant or plan to become pregnant or are breastfeeding.

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

3. What if I am taking other medicines?

Some medicines may interfere with Praluent 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 use Praluent?

- Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet.

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

5. What should I know while using Praluent?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using Praluent.• Follow your doctor's instructions carefully.• Tell your doctor if you are breastfeeding or
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	become pregnant while you are using Praluent.
Things you should not do	<ul style="list-style-type: none"> • Do not stop using this medicine or change the dosage without checking with your doctor. • Do not use Praluent if it is not clear to pale yellow or if it contains particles. • Do not give Praluent to children.
Looking after your medicine	<ul style="list-style-type: none"> • Refrigerate do not freeze, do not expose to heat and do not shake Praluent. • Keep in the outer carton in order to protect from light.

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

6. Are there any side effects?

Less serious side effects: allergic reaction symptoms include diarrhoea, rash or purple-coloured spots on the skin, hives and reddish skin spots sometimes with blisters, redness, swelling, pain or bruising where the injection is given, itching, painless swelling under the

skin, muscle pain, flu-like symptoms that include sore throat, runny nose or sneezing.

Serious side effects: shortness of breath, wheezing or difficulty breathing, swelling of the face, lips, tongue or other parts of the body.

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.

Praluent®

Active ingredient: alirocumab

Consumer Medicine Information (CMI)

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

Where to find information in this leaflet:

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

1. Why am I using Praluent?

Praluent contains the active ingredient alirocumab, a protein produced in Chinese hamster ovary cells.

Praluent is an injectable medicine and belongs to a group of medicines called monoclonal antibodies. Monoclonal antibodies are proteins that specifically

identify and attach to other proteins in the body. Praluent recognises and attaches to a protein called PCSK9.

PCSK9 lowers the level of a receptor called LDL-R, which is needed to remove LDL cholesterol.

Praluent blocks the PCSK9 protein, thereby increasing the LDL-R receptors that are available to remove LDL cholesterol. This results in lower levels of LDL cholesterol.

Praluent is used with other cholesterol lowering medicines to treat high levels of cholesterol in the blood.

Cholesterol is one of several fatty substances found in the bloodstream. Your total cholesterol is made up of mainly of Low Density Lipoprotein (LDL) and High Density Lipoprotein (HDL) cholesterol. Praluent reduces LDL cholesterol.

LDL cholesterol can build up in the walls of your arteries forming plaque. Eventually this plaque build-up can lead to a narrowing of the arteries.

This narrowing can slow or block blood flow to vital organs such as the heart and brain. This blocking of blood flow can result in a heart attack or stroke and can cause other health problems.

Praluent reduces the risk of heart attack, stroke, and chest pain that may be caused by too little blood and oxygen getting to the heart (angina), in adults with cardiovascular disease and high cholesterol levels in their blood.

Praluent is used in adults who cannot reduce their cholesterol levels by cholesterol lowering diet and exercise.

Praluent should be used with other lipid lowering medicines such as statins to treat high cholesterol and lipid disorders. When a statin cannot be used or does not work well, Praluent can be used alone or together with other cholesterol lowering medicines.

Praluent should be used along with cholesterol lowering diet and exercise as recommended by your doctor.

Your doctor, however, may have prescribed Praluent for another purpose. Ask your doctor if you have any questions about why it has been prescribed for you.

This medicine is only available with a doctor's prescription

2. What should I know before I use Praluent?

Warnings

Do not use Praluent if:

- you are allergic to alirocumab, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine.

- you are allergic to medicines or other products that are produced by DNA technology using Chinese Hamster Ovary cells.

Symptoms that may indicate an allergic reaction include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin

Tell your doctor if you are experiencing these symptoms.

Praluent should not be used after the expiry date (exp) printed on the pack.

If you use this medicine after the expiry date it may have no effect at all, or worse, an unexpected effect.

Praluent should not be used if the packaging is torn or shows signs of tampering.

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

Check with your doctor if you:

- allergies to any other medicines or substances such as foods, preservatives or dyes
- take any medicines for any other condition
- have any kidney or liver problems.

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 intend to become pregnant.

The effects of Praluent in pregnant women are not known. Therefore the use of this medicine in pregnant women is not recommended.

Talk to your doctor if you are breastfeeding or intend to breastfeed. It is not known whether Praluent passes into breast milk.

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 Praluent and affect how well it works.

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

4. How do I use Praluent?

How much to use

- The recommended starting dose of Praluent is either 75mg once every two weeks or 300 mg once

every four weeks. Your doctor may adjust your dose depending on your cholesterol levels.

- To administer the 300 mg dose, inject one 300 mg injection at one injection site, or inject two 150 mg injections, one after the other, at two different injection sites.
- Follow the instructions provided by your doctor and use Praluent until your doctor tells you to stop.

When to use Praluent

- Praluent is either used 75mg once every 2 weeks or 300 mg once every 4 weeks (monthly).

How to use Praluent

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 label or in this leaflet, ask your doctor or pharmacist for help.

Always check the Praluent label before each injection to make sure you are using the right injection.

Praluent is a clear to pale yellow liquid. Do not shake the Praluent liquid. Do not use Praluent if it is not clear to pale yellow or if it contains particles.

To avoid discomfort, Praluent should be allowed to warm to room temperature (up to 25°C) for 30 - 40 minutes before injection. Do not use a heat source to warm up Praluent. Do not put Praluent near direct sunlight.

The injection can be self-administered or given by another person, after proper training in injection technique.

- See the detailed "Instructions for Use" provided with the medicine for instructions about the right way to store, prepare, and use Praluent at home.
- Praluent is injected under the skin (subcutaneous injection) of your stomach area (abdomen), thigh or upper arm. Change the place that you inject each time so that you do not become sore in one area.
- After injecting Praluent, immediately throw away the used pre-filled pen or pre-filled syringe in a sharps container as instructed by your doctor or pharmacist.

Do not inject in an area where the skin is tender, reddened, bruised or hard. This may mean there is an infection.

Do not inject into the skin if it is sunburnt or injured.

Do not inject Praluent with other injectable medicines, at the same injection site.

How long to use Praluent

Praluent helps lower your cholesterol levels. It does not cure your condition. Therefore keep using Praluent as directed by your doctor. If you stop taking Praluent, your cholesterol levels may rise again.

If you forget to use Praluent

If you missed a dose of Praluent by less than 7 days, inject your missed dose as soon as you can, then have your next dose at your regular scheduled time. This will keep you on the original schedule.

If you missed a dose of Praluent by more than 7 days and you inject every 2 weeks, wait until your next scheduled dose to re-start Praluent. If you inject every 4 weeks, start a new schedule from the time you inject your missed dose.

If you are not sure when to inject Praluent, call your doctor, pharmacist or nurse.

It is important to use Praluent as prescribed by your doctor.

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

If you use too much Praluent

If you think that you have used too much Praluent, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre **(by calling 13 11 26)** 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.

You may need urgent medical attention. Keep telephone numbers of these places handy.

5. What should I know while using Praluent?

Things you should do

Always follow your doctor's instructions carefully.

Keep Praluent in a refrigerator (2°C - 8°C). Do not freeze. Do not expose to extreme heat.

Allow Praluent to warm to room temperature (up to 25°C) for 30 - 40 minutes before injection. Do not use a heat source to warm up Praluent. Do not put Praluent near direct sunlight.

It is important to keep using Praluent even if you feel well. Praluent helps to control your condition but does not cure it.

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

Remind any doctor, dentist or pharmacist you visit that you are using Praluent.

Call your doctor straight away if you:

- become pregnant while you are using Praluent.

Things you should not do

- Do not stop using this medicine suddenly or change the dosage without checking with your doctor.
- Do not give Praluent to anyone else, even if they have the same condition as you.
- Do not use Praluent to treat any other complaints unless your doctor tells you to.
- Do not shake Praluent.
- Do not use a heat source to warm up Praluent.
- Do not put Praluent near direct sunlight.
- Do not use Praluent if it is not clear to pale yellow or if it contains particles.
- Do not give Praluent to children. The safety and benefit of Praluent in children under the age of 18 years has not been established.

Looking after your medicine

- Keep Praluent in the pack to protect from light, until it is time to use it.
- Keep Praluent in a refrigerator (2°C - 8°C). Do not freeze. Do not expose to extreme heat.
- Keep Praluent in the refrigerator in an area where children cannot reach it.

If needed, the medicine may be kept outside the refrigerator below 25°C for a maximum of 30 days.

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

Store it in the refrigerator, away from 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.

When to discard your medicine

After removal from the refrigerator, Praluent must be used within 30 days or discarded.

Getting rid of any unwanted medicine

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

Do not use 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>Allergy:</p> <ul style="list-style-type: none">• a specific form of allergic reaction resulting in narrowing or blockage of blood vessels (hypersensitivity vasculitis). Symptoms include diarrhoea, rash or purple coloured spots on the skin (purpura). <p>General:</p> <ul style="list-style-type: none">• muscle pain• painless swelling under the skin (angioedema)• flu-like symptoms such as sore throat, runny nose, sneezing <p>Skin-related:</p> <ul style="list-style-type: none">• itching (pruritis)• hives (urticaria)• reddish skin spots sometimes with blisters (nummular eczema) <p>Injection site:</p>	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Less serious side effects	What to do
<ul style="list-style-type: none"> • redness, swelling, pain or bruising (haematoma) where the injection is given 	

Serious side effects

Serious side effects	What to do
<p>Allergy:</p> <ul style="list-style-type: none"> • shortness of breath • wheezing or difficulty in breathing • swelling of the face, lips, tongue or other parts of the body. 	<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 Praluent contains

Active ingredient (main ingredient)	<ul style="list-style-type: none">● Alirocumab
Other ingredients (inactive ingredients)	<ul style="list-style-type: none">● histidine● sucrose● polysorbate 20● water for injections

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

What Praluent looks like

Praluent is a clear to pale yellow sterile solution for injection available in a pre-filled pen or pre-filled syringe. (Aust R 238285, AUST R 238299, AUST R 238304, AUST R 238305, AUST R 377452)

Pre-filled pen:

Each pre-filled pen contains 1 mL or 2 mL of solution and is available in the following strengths:

75 mg/1 mL available in pack sizes of 1, 2 or 6

150 mg/1 mL available in pack sizes of 1, 2 or 6

300 mg/2 mL available in pack sizes of 1 or 3

Pre-filled syringe:

Each pre-filled syringe contains 1 mL of solution and is available in two different strengths:

75 mg/mL available in pack sizes of 1, 2 or 6

150 mg/mL available in pack sizes of 1, 2 or 6

Who distributes Praluent

Praluent is supplied in Australia by:

sanofi-aventis australia pty ltd

12-24 Talavera Road

Macquarie Park NSW 2113

Toll Free No: 1800 818 806

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