

Praluent[®]

Alirocumab (rch)

Consumer Medicine Information (CMI)

What is in this leaflet

This leaflet answers some common questions about Praluent.

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

All medicines have risks and benefits. Your doctor has weighed the risks of you using Praluent against the benefits this medicine is expected to have for you.

If you have any concerns about using this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

What Praluent is used for

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

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.

How it works

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.

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.

Before you use Praluent

When you must not use Praluent

Do not use Praluent if you have an allergy to:

- any medicine containing alirocumab (the active ingredient) or any of the ingredients listed at the end of this leaflet
- 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.

Do not give Praluent to children. The safety and benefit of Praluent in children under the age of 18 years has not been established.

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

Before you start to use it

Tell your doctor or pharmacist if you have allergies to any other medicines or substances such as foods, preservatives or dyes.

Tell 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.

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

It is not known whether Praluent passes into breast milk.

Tell your doctor if you have any kidney or liver problems.

Taking other medicines

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

Some medicines may be affected by Praluent or may affect how well Praluent works. You may need different amounts of your medicine, or you may need to take different medicines. Your doctor will advise you.

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.

How to use it

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 your Praluent at home.

If you do not understand the instructions on the label or in this leaflet, ask your doctor or pharmacist for help.

How much to inject

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 two 150 mg injections, one after the other, at two different injection sites.

Where to inject

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.

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 it

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 it

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.

If you use too much (overdose)

Immediately telephone your treating physician or Poisons Information Centre [Australia telephone 13 11 26; in New Zealand telephone 0800 POISON or 0800 764 766], or go to accident and emergency at your nearest hospital, if you think that you have used too much Praluent. 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.

While you are using Praluent

Things you must 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 become pregnant while you are using Praluent, tell your doctor.

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

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

Things you must not do

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 stop using your medicine or change the dosage without checking with your doctor.

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.

Side Effects

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

All medicines can have side effects. 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.

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

- redness, swelling, pain or bruising (haematoma) where the injection is given
- flu-like symptoms, such as sore throat, runny nose, sneezing
- muscle pain
- itching (pruritis)
- painless swelling under the skin (angioedema)

Tell your doctor as soon as possible if you notice any of the following:

- 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)
- hives (urticaria)
- reddish skin spots sometimes with blisters (nummular eczema)

If any of the following happen, tell your doctor immediately or go to the Accident and Emergency at your nearest hospital:

- shortness of breath
- wheezing or difficulty in breathing
- swelling of the face, lips, tongue or other parts of the body

Other side effects not listed above may occur in some patients. Tell your doctor if you notice anything making you feel unwell when you are using Praluent.

After using Praluent

Storage

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

Disposal

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.

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

Product description

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.

Pre-filled pen:

Each pre-filled pen 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

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

Ingredients

Active ingredients:

Alirocumab

Other ingredients:

- histidine
- sucrose
- polysorbate 20
- water for injections

Supplied by

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

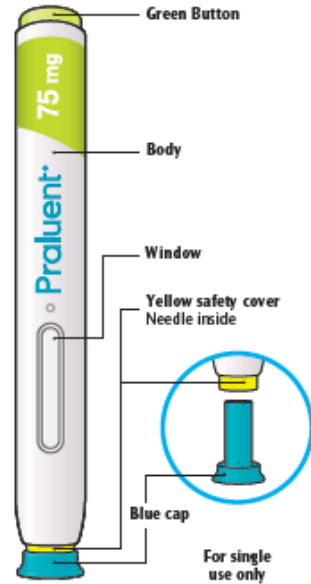
Praluent is supplied in New Zealand by:

sanofi-aventis new zealand ltd
56 Cawley St
Ellerslie, Auckland,
New Zealand
Toll Free No: 0800 283 684

This leaflet was prepared on 27
February 2020

AUST R 238285, AUST R 238299,
AUST R 238304, AUST R 238305.

The parts of the Praluent pen are shown in this picture.



Important information

- The 75 mg/mL pre-filled pen is a single use disposable pen. It contains 75 mg of Praluent (alirocumab) in 1 mL.
- The Praluent pen contains medicine prescribed by your doctor.
- The medicine is injected under your skin and can be given by yourself or someone else (caregiver).
- This pen can only be used for one single injection, and must be discarded after use.

Do

- ✓ Keep the Praluent pen out of the reach of children.
- ✓ Read all of the instructions carefully before using the Praluent pen.
- ✓ Follow these instructions every time you use a Praluent pen.
- ✓ Store unused pens in the refrigerator at 2°C to 8°C. For detailed storage conditions see Consumer Medicine Information overleaf.

Do not

- ✗ Do not touch the yellow safety cover.
- ✗ Do not use the pen if it has been dropped or damaged.
- ✗ Do not use the pen if the blue cap is missing or not securely attached.
- ✗ Do not re-use a pen.
- ✗ Do not shake the pen.
- ✗ Do not freeze the pen.
- ✗ Do not expose the pen to extreme heat.
- ✗ Do not expose the pen to direct sunlight.

Keep this leaflet. If you have questions, ask your doctor, pharmacist or nurse or call the sanofi-aventis number on the Consumer Medicine Information.

STEP A: GETTING READY FOR AN INJECTION

Before you start you will need:

- The Praluent pen, • cotton ball or gauze, • a puncture resistant container.

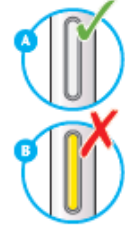
1 Look at the label on the pen.

- Check that you have the correct product and the correct dose.
- Check the use by date: do not use if this date has passed.



2 Look at the window.

- Check the liquid is clear, colorless to pale yellow and free from particles - if not, do not use (see picture A).
- You may see an air bubble. This is normal.
- Do not use if the window appears solid yellow (see picture B).



3 Before injection, let the pen warm up to room temperature (up to 25°C) for 30 to 40 minutes.

- Do not heat the pen, let it warm up on its own.
- Use the pen as soon as possible after it has warmed up.



4 Prepare the injection site.

- Wash your hands with soap and water and dry with a towel.
- You can inject into your:
 - thigh
 - belly (except for the 5 cm area around your navel)
 - upper arm (See picture).
- You can stand or sit to give yourself an injection.
- Make sure your skin in the injection area is clean and dry.
- Do not use skin that is tender, hard, red or hot.
- Do not use any area near a visible vein.
- Use a different area each time you inject.



STEP B: HOW TO INJECT

1 After completing all steps in 'STEP A: GETTING READY FOR AN INJECTION', pull off the blue cap.

- Do not pull off the cap until you are ready to inject.
- Do not put the blue cap back on.



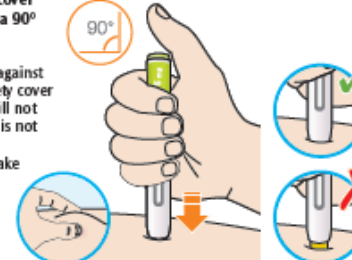
2 Hold the Praluent pen like this.

- Do not touch the yellow safety cover.
- Make sure you can see the window.



3 Press the yellow safety cover on your skin at roughly a 90° angle.

- Press and firmly hold the pen against your body until the yellow safety cover is no longer visible. The pen will not work if the yellow safety cover is not depressed fully.
- If needed, pinch the skin to make sure the injection site is firm.



4 Push and immediately release the green button with your thumb.

- You will hear a click. Your injection has now started.
- The window will start to turn yellow.



5 Keep holding the pen against your skin after releasing the button.

- The injection may take up to 20 seconds.



6 Check the window has turned yellow, before removing the pen.

- Do not remove the pen until the entire window has turned yellow.
- Your injection is complete, when the window has turned completely yellow, you may hear a second click.
- If the window does not turn completely yellow, call your doctor or pharmacist for help. Do not give yourself a second dose without speaking to your doctor, pharmacist or nurse.



7 Pull pen away from your skin.

- Do not rub the skin after the injection.
- If you see any blood, press a cotton ball or gauze on the site until the bleeding stops.

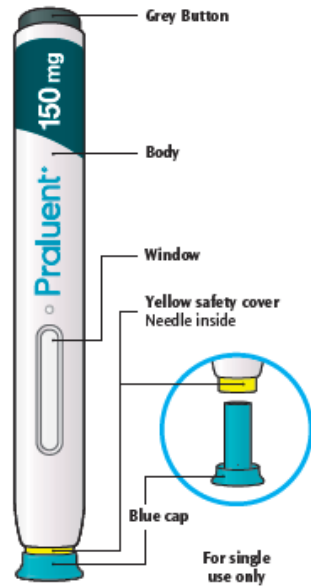


8 Discard pen and cap.

- Do not put the blue cap back on.
- Discard into a sharps container; ask your pharmacist how to throw away the pen.
- Always keep the container out of the reach of children.



The parts of the Praluent pen are shown in this picture.



Important information

- The 150mg/mL pre-filled pen is a single use disposable pen. It contains 150 mg of Praluent (alirocumab) in 1 mL.
- The Praluent pen contains medicine prescribed by your doctor.
- The medicine is injected under your skin and can be given by yourself or someone else (caregiver).
- This pen can only be used for one single injection, and must be discarded after use.

Do

- ✓ Keep the Praluent pen out of the reach of children.
- ✓ Read all of the instructions carefully before using the Praluent pen.
- ✓ Follow these instructions every time you use a Praluent pen.
- ✓ Store unused pens in the refrigerator at 2°C to 8°C. For detailed storage conditions see Consumer Medicine Information leaflet.

Do not

- ✗ Do not touch the yellow safety cover.
- ✗ Do not use the pen if it has been dropped or damaged.
- ✗ Do not use the pen if the blue cap is missing or not securely attached.
- ✗ Do not re-use a pen.
- ✗ Do not shake the pen.
- ✗ Do not freeze the pen.
- ✗ Do not expose the pen to extreme heat.
- ✗ Do not expose the pen to direct sunlight.

Keep this leaflet. If you have questions, ask your doctor, pharmacist or nurse or call the sanofi-aventis number on the Consumer Medicine Information.

STEP A: GETTING READY FOR AN INJECTION

Before you start you will need:

- The Praluent pen, • cotton ball or gauze, • a puncture resistant container.

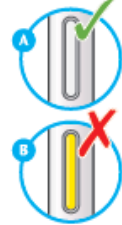
1 Look at the label on the pen.

- Check that you have the correct product and the correct dose.
- Check the use by date: do not use if this date has passed.



2 Look at the window.

- Check the liquid is clear, colorless to pale yellow and free from particles (see picture A) - if not, do not use.
- You may see an air bubble. This is normal.
- Do not use if the window appears solid yellow (see picture B)



3 Before injection, let the pen warm up to room temperature (up to 25°C) for 30 to 40 minutes.

- Do not heat the pen, let it warm up on its own.
- Use the pen as soon as possible after it has warmed up.



4 Prepare the injection site.

- Wash your hands with soap and water and dry with a towel.
- You can inject into your:
 - thigh
 - belly (except for the 5 cm area around your navel)
 - upper arm (See picture).
- You can stand or sit to give yourself an injection.
- Make sure your skin in the injection area is clean and dry.
- Do not use skin that is tender, hard, red or hot.
- Do not use any area near a visible vein.
- Use a different area each time you inject.



STEP B: HOW TO INJECT

1 After completing all steps in 'STEP A: GETTING READY FOR AN INJECTION', pull off the blue cap.

- Do not pull off the cap until you are ready to inject.
- Do not put the blue cap back on.



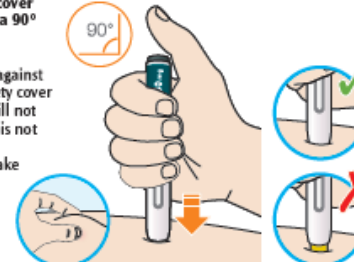
2 Hold the Praluent pen like this.

- Do not touch the yellow safety cover.
- Make sure you can see the window.



3 Press the yellow safety cover on your skin at roughly a 90° angle.

- Press and firmly hold the pen against your body until the yellow safety cover is no longer visible. The pen will not work if the yellow safety cover is not depressed fully.
- If needed, pinch the skin to make sure the injection site is firm.



4 Push and immediately release the grey button with your thumb.

- You will hear a click. Your injection has now started.
- The window will start to turn yellow.



5 Keep holding the pen against your skin after releasing the button.

- The injection may take up to 20 seconds.



6 Check the window has turned yellow, before removing the pen.

- Do not remove the pen until the entire window has turned yellow.
- Your injection is complete, when the window has turned completely yellow, you may hear a second click.
- If the window does not turn completely yellow, call your doctor or pharmacist for help. Do not give yourself a second dose without speaking to your doctor, pharmacist or nurse.



7 Pull pen away from your skin.

- Do not rub the skin after the injection.
- If you see any blood, press a cotton ball or gauze on the site until the bleeding stops.



8 Discard pen and cap.

- Do not put the blue cap back on.
- Discard into a sharps container; ask your pharmacist how to throw away the pen.
- Always keep the container out of the reach of children.

