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 taking Praluent against the benefits this medicine is expected to have for you.

If you have any concerns about taking 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.

Praluent is a medicine used to treat hypercholesterolemia, which is when you have high levels of cholesterol (a type of fat in the blood). Praluent is also used to treat dyslipidemia, which is a condition where you have raised levels of lipids (fats and oils that the body uses to store energy) in the blood.

Praluent helps to reduce ‘bad’ cholesterol (low density lipoprotein (LDL)).

Praluent can be used by itself or with other lipid lowering medicines such as statins or ezetimibe, to treat high cholesterol and lipid disorders.

Praluent should be used along with a cholesterol lowering diet and any other lifestyle changes 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 ‘bad’ cholesterol.

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

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 taking 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.

**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 solution that should not be shaken before use. 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.

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

**What dose to inject**

The recommended starting dose of Praluent is 75mg or 150mg (once every 2 weeks) or 300mg (once every 4 weeks). Your doctor may adjust your dose (up and down) depending on your cholesterol levels.

**How much to inject**

Inject the full dose of Praluent prescribed to you by your doctor.

**When to inject**

Praluent should be injected once every 2 weeks (for the 75mg or 150mg dose) or once every 4 weeks (for the 300mg dose). Your doctor will tell you how often to inject. To give the 300mg dose, give two 150mg injections in a row 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 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 miss a dose of Praluent, inject your missed dose as soon as possible. Then inject your next dose as you would have on your original schedule. In case you are not sure when to inject Praluent, call your doctor or pharmacist.

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

**If you use too much (overdose)**

Immediately telephone your treating physician or Poisons Information Centre [Telephone 0800 POISON or 0800 764 766], or go to accident and emergency at your nearest hospital, if you think that you have taken 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 taking 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.
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 taking your medicine or lower the dosage without checking with your doctor.

**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 (hematoma) where the injection is given
- flu-like symptoms
- itching (pruritis)
- a specific form of allergic reaction resulting in narrowing or blockage of blood vessels (hypersensitivity vasculitis). Symptoms include diarrhea, 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.

**Pre-filled pen:**

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

- 75 mg/mL (green button) available in pack sizes of 1, 2 or 6
- 150 mg/mL (grey button) 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 (green plunger) available in pack sizes of 1, 2 or 6
- 150 mg/mL (grey plunger) 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 New Zealand by:

sanofi-aventis new zealand limited
56 Cawley St
Ellerslie, Auckland,
New Zealand

Toll Free No: 0800 283 684

This leaflet was prepared on 31 May 2018

pral-ccdsv3-cmiv3-31may18