

## What is in this leaflet

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## What Praluent is used for

Praluent is used along with diet and maximally tolerated statin therapy in adults with heterozygous familial hypercholesterolemia (an inherited condition that causes high levels of LDL) or atherosclerotic heart problems, who need additional lowering of LDL cholesterol. The effect of PRALUENT on heart problems such as heart attacks, stroke, or death is not known.

## How Praluent works

Praluent helps lower your levels of “bad” cholesterol (also called “LDL cholesterol”). Praluent blocks a protein called PCSK9.

- PCSK9 is a protein secreted by liver cells.
- “Bad” cholesterol is normally removed from your blood by binding to specific “receptors” (docking stations) in your liver.
- PCSK9 lowers the number of these receptors in the liver – this causes your “bad” cholesterol to be higher than it should.
- By blocking PCSK9, Praluent increases the number of receptors available to help remove the “bad” cholesterol – this lowers your “bad” cholesterol levels.

## Before you use Praluent

### When you must not use it

If you are allergic to alirocumab or any of the other ingredients of this medicine.

### Before you start to use it

### Warnings and precautions

Talk to your doctor, pharmacist or nurse about all your medical conditions, including allergies, before using Praluent.

If you develop a serious allergic reaction, stop using Praluent, talk to your doctor right away. Sometimes serious allergic reactions such as hypersensitivity (difficulties breathing), nummular eczema (reddish skin spots sometimes with blisters), and hypersensitivity vasculitis (which is a specific form of a hypersensitivity reaction with symptoms such as diarrhoea, with a rash, or purple-coloured skin spots on the skin) have occurred in clinical studies.

Tell your doctor if you have kidney or liver disease before using this medicine, because Praluent has been studied in few patients with severe kidney disease and not in patients with severe liver disease.

### Children and adolescents

Praluent is not recommended for children and adolescents under 18 years old. This is because there is no experience of using the medicine in these age groups.

### Other medicines and Praluent

Tell your doctor, pharmacist or nurse if you are using, have recently used or might use any other medicines.

### Pregnancy and breast-feeding

Praluent is not recommended during pregnancy or breast-feeding.

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before using this medicine.

### Driving and using machines

This medicine is not expected to have any effect on your ability to drive or use machines.

## How to use Praluent

Always use this medicine exactly as your doctor, pharmacist or nurse has told you. Check with your doctor, pharmacist or nurse if you are not sure.

## How much to inject/How long to use it

Your doctor will tell you which dose is right for you and how often to inject (75 mg once every 2 weeks, or 300 mg once every 4 weeks/monthly). Your doctor will check your cholesterol levels and may adjust the dose (up or down) during treatment. Always check the label of your pen to make sure you have the right medicine and the right strength.

### When to inject

Inject Praluent once every 2 weeks (for the 75 mg dose), or once every 4 weeks/monthly (for the 300 mg dose). To give the 300 mg dose, give two 150 mg injections in a row at two different injection sites.

### Before you inject

Read the detailed instructions for use leaflet before you inject Praluent.

### Where to inject

Read the detailed instructions for use leaflet on where to inject.

### Learning how to use the pre-filled pen

Before you use the pen for the first time, your doctor, pharmacist or nurse will show you how to inject Praluent.

- Always read the "Instructions for Use" provided in the box.
- Always use the pen as described in the "Instructions for Use".

## While you are using it

### If you use more Praluent than you should

If you use more Praluent than you should, talk to your doctor, pharmacist or nurse.

### If you forget to use Praluent

If you forget to use Praluent or are not able to take the dose at your regular time, inject your missed dose as soon as you remember, within 7 days. Then, if you inject every 2 weeks take your next dose in 2 weeks from the day you missed your dose or if you inject every 4 weeks take your

next dose in 4 weeks from the day you missed your dose. This will put you back on your original schedule. If you missed a dose by more than 7 days and you inject every 2 weeks wait until your next scheduled dose to re-start Praluent or if you inject every 4 weeks start a new schedule from the time you remember to take your dose. If you are not sure when to re-start Praluent, ask your doctor.

### If you stop using Praluent

Do not stop using Praluent without talking with your doctor. If you stop using Praluent, your cholesterol levels can increase.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

### **Side effects**

Like all medicines, this medicine can cause side effects, although not everybody gets them.

If you develop a serious allergic reaction, stop using Praluent, talk to your doctor right away. Sometimes serious allergic reactions such as hypersensitivity (difficulties breathing), nummular eczema (reddish skin spots sometimes with blisters), and hypersensitivity vasculitis (which is a specific form of a hypersensitivity reaction with symptoms such as diarrhoea, with a rash, or purple-coloured skin spots on the skin) have occurred (may affect up to 1 in 1,000 people).

Other side effects are:

**Common** (may affect up to 1 in 10 people)

- redness, itching, swelling, pain/tenderness where the medicine was injected (local injection site reactions)
- upper respiratory tract signs or symptoms such as sore throat, running nose, sneezing
- itching (pruritus).

**Rare** (may affect up to 1 in 1,000 people)

- red and itchy raised bumps or hives (urticaria)

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835400, or visiting the website [npra.moh.gov.my](http://npra.moh.gov.my) (Public > Reporting Medicinal Problems /Side Effects /AEFI /).

### **Storage and Disposal of Praluent**

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the label and carton after EXP. The expiry date refers to the last day of that month.

Store in a refrigerator (2°C to 8°C). Do not freeze.

Keep the pen in the outer carton in order to protect from light.

If needed, individual pre-filled pens may be kept outside the refrigerator below 25°C for a maximum of 30 days. Protect from light. After removal from the refrigerator, Praluent must be used within 30 days or discarded.

Do not use this medicine if it looks discoloured or cloudy, or if it contains visible flakes or particles.

After use put the pen into a puncture-resistant container. Always keep the container out of the sight and reach of children. Ask your doctor, pharmacist or nurse how to throw away the container. Do not recycle the container.

Do not throw away any medicines via wastewater or household waste.

Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

### **Product description**

#### What it looks like

Praluent is a clear, colourless to pale yellow solution for injection that comes in a pre-filled pen.

Each pre-filled pen with green button contains 1 ml of solution, delivering one single dose of 75 milligrams.

It is available in pack size of 1, 2 or 6 pre-filled pens.

Each pre-filled pen with grey button contains 1 ml of solution, delivering one single dose of 150 milligrams.

It is available in pack size of 1, 2 or 6 pre-filled pens.

Not all pack sizes may be marketed.

### Ingredients

- The active substance is alirocumab. Each single-use pen contains either 75 milligrams (75 milligrams per ml) or 150 milligrams (150 milligrams per ml) of alirocumab.

- The other ingredients are histidine, sucrose, polysorbate 20 and water for injection.

### Registration Number

75 mg/ml: MALxxxxxxxxAZ

150 mg/ml: MALxxxxxxxxAZ

### **Manufacturer**

Sanofi-Aventis Deutschland GmbH  
65926 Frankfurt am Main, Germany.

### **Product Registration Holder**

sanofi-aventis(Malaysia)Sdn. Bhd.  
Unit TB-18-1, Level 18, Tower B, Plaza 33, No.1 Jalan Kemajuan, Seksyen 13, 46200 Petaling Jaya, Selangor Darul Ehsan, Malaysia.

### **Date of revision**

24/5/2017

(USPI Apr17 & EU SmPC Oct16).

### Serial no.

75 mg/ml: BPFK (R3)17/006

150 mg/ml: BPFK (R3)17/004