

Package leaflet:
Information for the user

Praluent® 75 mg

solution for injection in a pre-filled pen

Praluent® 150 mg

solution for injection in a pre-filled pen

alirocumab

REGENERON
SANOFI

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Praluent is and what it is used for
2. What you need to know before you use Praluent
3. How to use Praluent
4. Possible side effects
5. How to store Praluent
6. Contents of the pack and other information

1. What Praluent is and what it is used for

What Praluent is

- Praluent contains the active substance alicumab.
- Praluent is a monoclonal antibody (a type of specialised protein designed to attach to a target substance in the body). Monoclonal antibodies are proteins that recognise and bind to other unique proteins. Alicumab binds to PCSK9.

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.

What Praluent is used for

- Adults with high cholesterol levels in their blood (hypercholesterolaemia [heterozygous familial and non-familial] or mixed dyslipidaemia).
- Adults with high cholesterol levels in their blood and with cardiovascular disease to reduce cardiovascular risk.

It is given:

- together with a statin (a commonly used medicine that treats high cholesterol) or other cholesterol lowering medicines, if the maximum dose of a statin does not lower levels of cholesterol sufficiently or,
 - alone or together with other cholesterol lowering medicines when statins are not tolerated or cannot be used.
- Continue to follow your cholesterol-lowering diet while taking this medicine.

2. What you need to know before you use Praluent

Do not use Praluent

- if you are allergic to alicumab or any of the other ingredients of this medicine (listed in section 6).

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. For allergic reactions that may occur while taking Praluent, see section 4.

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.

3. 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

Your doctor will tell you which dose is right for you and how often to inject (75 mg or 150 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 or 150 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”.

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 miss a dose of Praluent, inject your missed dose as soon as you can. Then take your next dose at your regular scheduled time. This will keep you on the original schedule. If you are not sure when to inject Praluent, call your doctor, pharmacist or nurse.

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.

4. Possible 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)

Not Known

The following side effects have been reported since the marketing of Praluent, but how often they occur is not known:

- flu-like illness

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

United Kingdom

You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

Ireland

You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie

Malta

You can also report side effects directly via ADR Reporting www.medicinesauthority.gov.mt/adrportal

By reporting side effects you can help provide more information on the safety of this medicine.

<MAT>746994



5. How to store 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.

6. Contents of the pack and other information

What Praluent contains

- The active substance is alicumab. Each single-use pen contains either 75 milligrams (75 milligrams per ml) or 150 milligrams (150 milligrams per ml) of alicumab.
- The other ingredients are histidine, sucrose, polysorbate 20 and water for injection.

What Praluent looks like and contents of the pack

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 presentations and pack sizes may be marketed.

Marketing Authorisation Holder

sanofi-aventis groupe
54, rue La Boétie
F – 75008 Paris
France

Manufacturer

Genzyme Ireland Ltd
IDA Industrial Park
Old Kilmeaden Road
Waterford
Ireland

This leaflet was last revised in March 2019

Detailed information on this medicine is available on the European Medicines Agency web site: <http://www.ema.europa.eu>.

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

Malta

Sanofi Malta Ltd.
Tel: +353 21493022

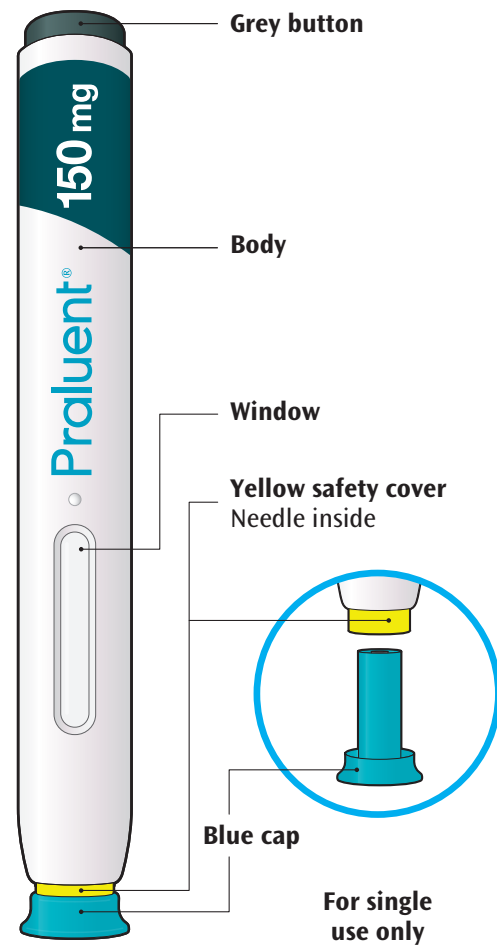
Ireland

sanofi-aventis Ireland Ltd. T/A SANOFI
Tel: +353 (0) 1 403 56 00

United Kingdom

Sanofi
Tel: +44 (0) 845 372 7101

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



Important information

- The device is a single use pre-filled pen. It contains 150 mg of Praluent (aliocumab) in 1 ml.
- 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 thrown away after use.

Do

- ✓ Keep the Praluent pen out of the sight and 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 separate package leaflet for Praluent.

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 direct sunlight.

Keep this leaflet. If you have questions, ask your doctor, pharmacist or nurse or call the Sanofi number on the package leaflet.

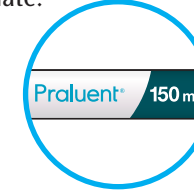
STEP A: Getting ready for an injection

Before you start you will need:

- the Praluent pen
- alcohol wipes
- cotton ball or gauze
- a puncture-resistant container (see Step B, 8).

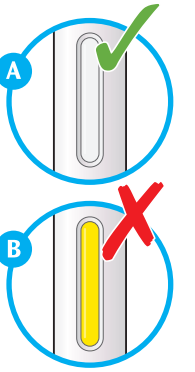
1 Look at the label on the pen.

- 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, colourless 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).

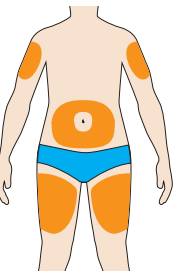


3 Let the pen warm up at room temperature for 30 to 40 minutes.

- Do not heat the pen, let it warm up on its own.
- Do not put the pen back in the refrigerator.

4 Prepare the injection site.

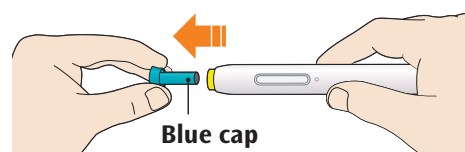
- Wash your hands with soap and water and dry with a towel.
- You can inject into your:
 - thigh
 - belly (except for the 5 cm area around your navel)
 - outer side of your upper arm (See picture).
- Do not use skin that is tender, hard, red or hot.
- Do not use any area near a visible vein.
- Use a different spot each time you inject.
- Do not inject Praluent with other injectable medicines at the same spot.



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.



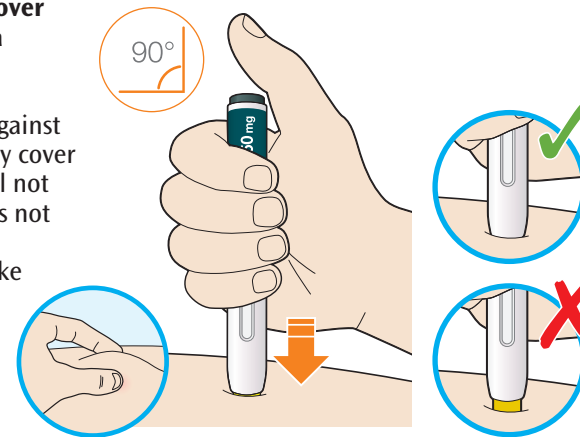
2 Hold the Praluent pen like this.

- 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.



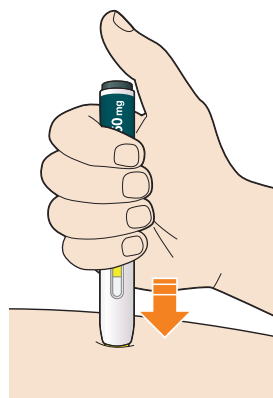
4 Push and immediately release the grey button with your thumb.

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



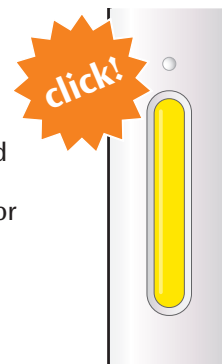
5 Keep holding the pen against your skin after releasing the button.

- The injection may take up to 20 seconds.



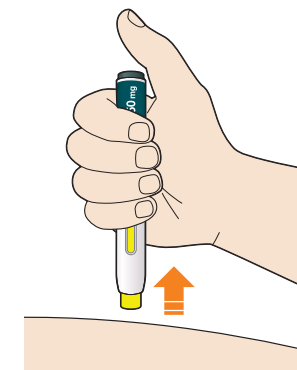
6 Check if the window has turned yellow, before removing the pen.

- 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 Sanofi 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 Throw away pen and cap.

- Do not put the blue cap back on.
- Throw away pen and cap into a puncture-resistant container immediately after use.
- Ask your doctor, pharmacist or nurse how to throw away the container.
- Always keep the container out of the sight and reach of children.

