

The format of this leaflet was determined by the Ministry of Health and its content was checked and approved by the Ministry of Health in April 2017, and updated in November 2018, in accordance with the Ministry of Health guidelines.

PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS’ REGULATIONS (PREPARATIONS) - 1986

The medicine is dispensed with a doctor’s prescription only

PRALUENT 75 MG

Solution for subcutaneous injection

PRALUENT 150 MG

Solution for subcutaneous injection

SANOFI

Active ingredient:

Praluent 75 mg – each pre-filled pen/syringe contains 75 mg alirocumab.
Praluent 150 mg – each pre-filled pen/syringe contains 150 mg alirocumab.
Inactive ingredients: see section 6.

Read this leaflet carefully in its entirety before using the medicine.

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Keep this leaflet; you may need to read it again.
This leaflet contains concise information about the medicine.
If you have further questions, refer to the doctor, pharmacist or nurse.
This medicine has been prescribed for you. Do not pass it on to others. It may harm them even if it seems to you that their medical condition is similar.
Praluent is not intended for use in children and adolescents under 18 years of age.

1. WHAT PRALUENT IS INTENDED FOR

For treatment of adults with high cholesterol levels in their blood (primary hypercholesterolemia [heterozygous familial or non-familial] or mixed dyslipidemia) in combination with a suitable diet. It is given:
* In combination with statins or with statins and other blood-fat lowering medicines if the maximum dose of a statin does not lower levels of cholesterol sufficiently or
as a monotherapy (Praluent only) or in combination with other blood-fat lowering medicines when statins are not tolerated or cannot be used.

Therapeutic group:

Alirocumab is a human monoclonal antibody that aids in lower blood cholesterol levels.
Praluent helps lower your levels of “bad” cholesterol (also called LDL cholesterol).
Praluent blocks the 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.

2. BEFORE USING THE MEDICINE

☒ **Do not use this medicine if:**

- you are allergic to alirocumab or to any of the other ingredients in this medicine (see section 6).

Special warnings regarding use of the medicine

Talk to the doctor, pharmacist or nurse about your medical condition, 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 diarrhea, with a rash or purple-colored skin spots on the skin) have occurred in clinical studies.
For information on 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 intended for use in children and adolescents under 18 years of age. This is because there is no experience of using the preparation in these age groups.

If you are taking, or have recently taken, other medicines, including non-prescription medicines or nutritional supplements, tell the doctor or pharmacist.

Pregnancy and breastfeeding

Praluent is not recommended during pregnancy or breastfeeding. If you are pregnant or breastfeeding, think you may be pregnant or are planning to become pregnant, consult the doctor or pharmacist before taking 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 SHOULD YOU USE THE MEDICINE?

Always use according to the doctor's instructions exactly. Check with the doctor or pharmacist if you are uncertain.
Your doctor will determine the proper dose for you and how often to inject (75 mg or 150 mg every two weeks, or 300 mg once every 4 weeks).
Your doctor will check your cholesterol levels and may adjust the dose (up or down) during treatment.
Check the label before each injection; make sure that the name of the medicine and the strength are correct.
Inject Praluent once every two weeks (for the 75 mg or 150 mg dose), or once every 4 weeks (for the 300 mg dose). In order to inject a dose of 300 mg, administer two injections of 150 mg, one after the other, at two different injection sites.

Instructions for use

Before you use the pen/syringe 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 package.
Always use the pen/syringe as described in the “**Instructions for Use**”.

If you use more Praluent than you should

If you use more Praluent than you should, refer to a 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 **according to the usual schedule**. This will keep you on the original schedule. If you are not sure when to inject Praluent, consult the doctor, pharmacist or nurse.
Do not inject a double dose to compensate for a forgotten dose.

If you stop using Praluent

Do not stop using Praluent without consulting the doctor. If you stop using Praluent, your cholesterol levels can increase.
Do not take medicines in the dark! Check the label and the dose each time you take a medicine. Wear glasses if you need them.
If you have any further questions regarding use of the medicine, consult a doctor, pharmacist or nurse.

4. SIDE EFFECTS

As with any medicine, use of Praluent may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.
If you develop a serious allergic reaction, stop using Praluent and refer to your doctor right away.
Sometimes (up to 1 in 1,000 people) 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 diarrhea, with a rash, or purple colored skin spots on the skin) have occurred.

Additional side effects:

Common side effects - effects that occur in 1-10 in 100 users:

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

Rare side effects - effects that occur in 1-10 in 10,000 users:

- red raised and itchy bumps or hives (urticaria)

Unknown frequency:

The following side effect has been reported after marketing of Praluent was initiated, but its frequency is unknown:
• flu-like illness.

If a side effect occurs, if one of the side effects worsens or if you are suffering from a side effect not mentioned in the leaflet, consult the doctor.

Side effects can be reported to the Ministry of Health by clicking on the link “Report Side Effects of Drug Treatment” found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link:
<https://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffectMedic@moh.gov.il>

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5. HOW SHOULD THE MEDICINE BE STORED?

Avoid poisoning! This medicine and any other medicine must be kept in a safe place out of the reach of children and/or infants in order to avoid poisoning.
This medicine was prescribed to treat your ailment; in another patient, it can cause harm. Do not give this medicine to your relatives, neighbors or acquaintances.
Do not use the medicine after the expiry date (exp. date) that appears on the package and on the pen/syringe. The expiry date refers to the last day of that month.
Store in a refrigerator (between 2°C and 8°C). Do not freeze.
Keep the pre-filled pens/syringes in the original package in order to protect from light.
If needed, individual pre-filled pens/syringes 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 the solution looks discolored, cloudy, or if it contains visible flakes or particles.
Do not store different medications in the same package.
After use, put the pen/syringe into a puncture-resistant container. Keep the container out of the reach of children. Ask the doctor, pharmacist or nurse how to throw away the container. Do not recycle the container.
Do not throw away medicines via household waste or wastewater. Ask your pharmacist how to throw away medicines you no longer need. These measures will help protect the environment.

6. FURTHER INFORMATION

In addition to the active ingredient, each pen/syringe also contains the following inactive ingredients:

L-Histidine/L-Histidine monohydrochloride monohydrate, Sucrose, Polysorbate 20, Water for injection.

What the medicine looks like and the contents of the package:

Praluent is a clear, colorless to light yellow solution provided in a pre-filled pen/syringe.

Praluent 75 mg: Each pre-filled pen with a green button/pre-filled syringe with a green plunger contains 1 ml of solution, and releases a single dose of 75 mg.

It is available in pack size of 1, 2 or 6 pre-filled pens/syringes; not all pack sizes are marketed.

Praluent 150 mg: Each pre-filled pen with a grey button/pre-filled syringe with a grey plunger contains 1 ml of solution, and releases a single dose of 150 mg.

It is available in pack size of 1, 2 or 6 pre-filled pens/syringes; not all pack sizes are marketed.

This leaflet does not contain all the information about the preparations. If you have any question or are uncertain about something, please refer to a doctor.

License holder name and address: sanofi-aventis Israel Ltd., 10 Beni Gaon Street, Netanya.

Manufacturer name and address: Sanofi-Aventis Group, France.

Registration number of the medicine in the National Drug Registry of the Ministry of Health:

Praluent 75 mg: 156-08-34583

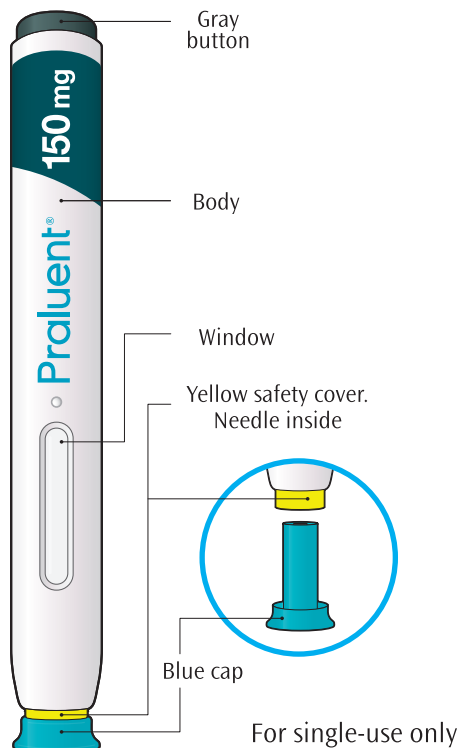
Praluent 150 mg: 156-09-34568

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INSTRUCTIONS FOR USE

Praluent 150 mg solution for injection in a pre-filled pen

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



Important information

- * The device is a single use pre-filled pen. The pen contains 150 mg of Praluent (alirocumab) in 1 ml.
- * The medicine is injected under your skin and can be given by yourself or by someone else (a 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 reach and sight of children
- ✓ Read all of the instructions carefully before using Praluent pen
- ✓ Follow the instructions every time you use a Praluent pen
- ✓ Store unused pens in the refrigerator, at a temperature between 2-8°C. For detailed storage conditions, see Praluent 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 direct sunlight.

Keep these instructions. If you have questions, refer to a doctor, pharmacist or nurse.

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).

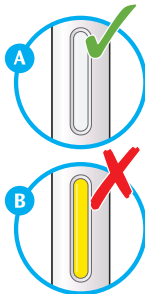
1. Look at the label on the pen

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



2. Look at the window

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

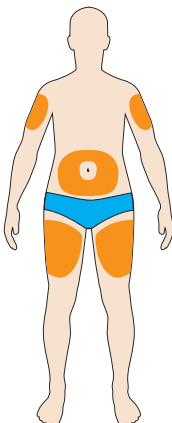


3. Let the pen warm up at room temperature for 30 to 40 minutes.

- * Do not heat the pen, let it warm up on its own
- * Use the pen as soon as possible after it has warmed up
- * Do not put the pen back in the refrigerator

4. Prepare the injection site

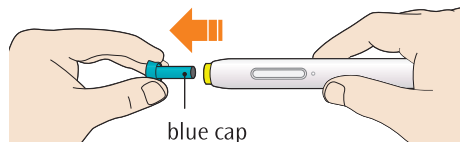
- * Wash your hands with soap and water and dry with a towel
- * You can inject into your:
 - thigh
 - belly (except for the 5 cm area around the navel)
 - outer side of the upper arm (see picture)
- * You can stand or sit to give yourself an injection
- * Clean the skin in the injection area with an alcohol wipe
- * Do not inject into skin that is tender, hard, red or hot
- * Do not inject into an area near a visible vein
- * Inject into a different spot each time
- * Do not inject Praluent with other injectable medicines at the same spot.



STEP B: HOW TO INJECT

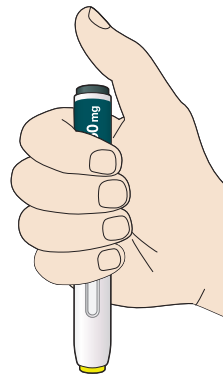
1. After completing all steps in “Step A: Getting ready for an injection”, pull off the blue cap.

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



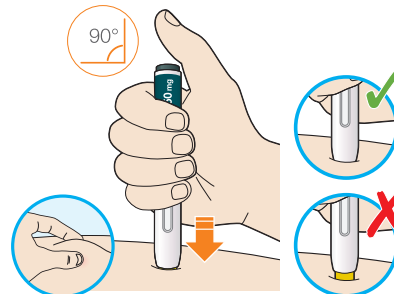
2. Hold the Praluent pen like this

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



3. Press the yellow safety cover onto 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 that the injection site is firm.



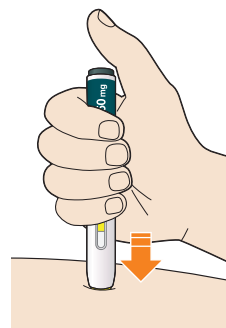
4. Push and immediately release the gray button with your thumb.

- * 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

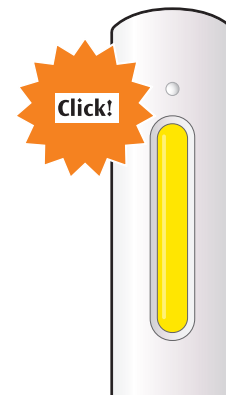
- * The injection may take up to 20 seconds.



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

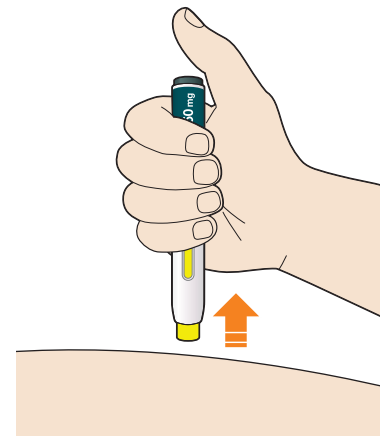
- * Do not remove the pen until the entire window has turned yellow.

- * 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, consult a 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 injection site until the bleeding stops.



8. Throw away the pen and cap.

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

