

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PrPRALUENT®

alirocumab injection

solution for subcutaneous injection

75 mg/mL and 150 mg/mL

Read this carefully before you start taking **PRALUENT** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **PRALUENT**.

What is PRALUENT used for?

PRALUENT is used:

- To reduce the risk of heart attack, stroke, and certain types of heart procedures (to restore blood flow to the heart) in adults with cardiovascular disease.
- To reduce low density lipoprotein cholesterol (LDL-C) levels in adults with high cholesterol levels (hypercholesterolemia, heterozygous familial and non-familial).

PRALUENT can be used along with lifestyle changes, by itself or with other medicines (such as statins or ezetimibe) to treat patients with high cholesterol. Continue to follow your cholesterol-lowering diet while taking this medicine.

It is not known if PRALUENT is safe and effective in children.

How does PRALUENT work?

PRALUENT is an injectable medicine that belongs to a type of medicines called PCSK9 inhibitors.

- PRALUENT is a fully human monoclonal antibody that blocks a protein called PCSK9 (proprotein convertase subtilisin kexin type 9).
- PCSK9 is a protein secreted by liver cells.
- LDL (“bad”) cholesterol is normally removed from the blood by binding to specific receptors (docking stations) on liver cells. PCSK9 lowers the number of LDL receptors available to remove LDL cholesterol from the blood.
- PRALUENT blocks PCSK9 and thereby increases the number of receptors available to remove LDL cholesterol from the blood. This results in lower LDL cholesterol levels.

What are the ingredients in PRALUENT?

Medicinal ingredients: alirocumab

Non-medicinal ingredients: histidine, polysorbate 20, sucrose and water for injection

PRALUENT comes in the following dosage form:

- Pre-filled pen

Do not use PRALUENT if:

- you are allergic to alirocumab or to any of the other ingredients in this medicine

To help avoid side effects and ensure proper use of PRALUENT, talk to your healthcare professional about any health conditions or problems you may have before taking this medicine, including if you:

- have allergies. If you have a serious allergic reaction, stop using PRALUENT and tell your doctor or pharmacist.
- are pregnant or intend to get pregnant. Tell your doctor or pharmacist before using this medicine. The use of PRALUENT is not recommended during pregnancy.
- are breastfeeding or plan to breastfeed. Tell your doctor or pharmacist before using this medicine. The use of PRALUENT is not recommended during breast-feeding.

Other warnings you should know about:

The safety and efficacy have not been established in children and adolescents less than 18 years of age. Therefore, the use of PRALUENT is not recommended in this age group.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

How to take PRALUENT:

PRALUENT is injected under the skin (subcutaneous use) of your upper leg (thigh), stomach area (abdomen), or upper arm.

Always check the label of your pre-filled pen to make sure you have the correct product and the correct strength of PRALUENT before each injection.

Remove PRALUENT pen from refrigerator approximately 30 to 40 min before injection to allow the solution to come to room temperature.

Choose a different spot each time you inject (e.g. right thigh then left thigh, or right abdomen then left abdomen).

Do not inject into areas where the skin is injured, tender, hard, red or hot.

Do not inject PRALUENT together with other injectable medicines at the same injection site.

PRALUENT comes as a single-dose (1 time) pre-filled pen (autoinjector). Your healthcare provider will prescribe the dose that is best for you.

Before starting PRALUENT, you should be on a diet to lower your cholesterol. You should stay on this cholesterol lowering diet while taking PRALUENT.

If your doctor has prescribed PRALUENT along with a statin or other cholesterol lowering medicine, follow your doctor's instructions on how to take these medicines together. In this case, please read the dosage instructions in the package leaflet of the other medicines.

Ask your doctor if you have any further questions on how to use PRALUENT.

Learning how to use the pre-filled pen

Before you use the pre-filled 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 pre-filled pen as described in the "Instructions for Use".

Usual dose:

PRALUENT is available as 75 mg or 150 mg for subcutaneous administration. Your doctor will tell you which dosage (75 mg or 150 mg every 2 weeks or 300 mg every 4 weeks) is right for you.

To give the 300 mg dose, give two 150 mg injections in a row at two different injection sites.

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

Overdose:

If you think you have taken too much PRALUENT, contact your healthcare professional, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

Missed Dose:

If you miss a dose of PRALUENT, inject your missed dose as soon as you are able to do so, within 7 days. Then take your next dose at your regular scheduled time:

- If you take PRALUENT every 2 weeks, take your next dose 2 weeks from the day you missed your dose.
- If you take PRALUENT every 4 weeks, take your next dose 4 weeks from the day you missed your dose.

If you miss a dose by more than 7 days:

- If you take PRALUENT every 2 weeks, wait until your next dose scheduled to re-start.
- If you take PRALUENT every 4 weeks, start a new schedule from the time you remember to take your dose.

In case you are not sure when to inject PRALUENT, call your doctor, nurse or pharmacist.

What are possible side effects from using PRALUENT?

PRALUENT may cause allergic reactions that can be severe and require treatment in a hospital. Call your healthcare provider or go to the nearest hospital emergency room right away if you have any symptoms of an allergic reaction, including a severe rash, redness, severe itching, swelling of the face, lips, throat or tongue, or trouble breathing.

These are not all the possible side effects you may feel when taking PRALUENT. If you experience any side effects not listed here, contact your healthcare professional. Please also see "Do not use PRALUENT if" and "Other warnings you should know about".

Common (may affect up to 1 in 10 people)

- Redness, swelling, pain, tenderness, or bruising (hematoma) where the injection is given (local injection site reactions)
- Symptoms of the common cold
- Itching (pruritus)

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

- Allergic reactions
- Hypersensitivity vasculitis: a specific form of allergic reaction, with symptoms such as rash or purple-colored spots on the skin, diarrhea.
- Hives (urticaria)
- Reddish skin spots, sometimes with blisters (nummular eczema)

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
RARE (may affect up to 1 in 1,000 people)			
Allergic reactions			✓
Hypersensitivity vasculitis, which is a specific form of allergic reaction. Symptoms may include diarrhea, rash, or purple-colored spots on the skin (purpura)			✓

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-healthproducts/medeffect-canada.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

Keep out of reach and sight of children.

Do not use this medicine after the expiry date which is stated on the label and carton.

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

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

Do not expose to extreme heat.

PRALUENT should be allowed to warm to room temperature prior to use. PRALUENT should be used as soon as possible after it has warmed up (in 30 to 40 min). When taken out of the refrigerator to warm up the pen, do not put near a heat source or in direct sunlight. Do not keep PRALUENT for more than 30 days at room temperature.

Do not use this medicine if the solution is discolored 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 reach of children. Ask your health care provider or pharmacist 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.

If you want more information about PRALUENT:

- Talk to your healthcare professional.
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website (<http://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the manufacturer's website: www.sanofi.ca, or by calling 1-800-265-7927.

This leaflet was prepared by Sanofi-aventis Canada Inc.

Last revised: -February 17, 2023

INSTRUCTIONS FOR USE

Praluent (alirocumab) 75 mg solution for injection in a pre-filled pen

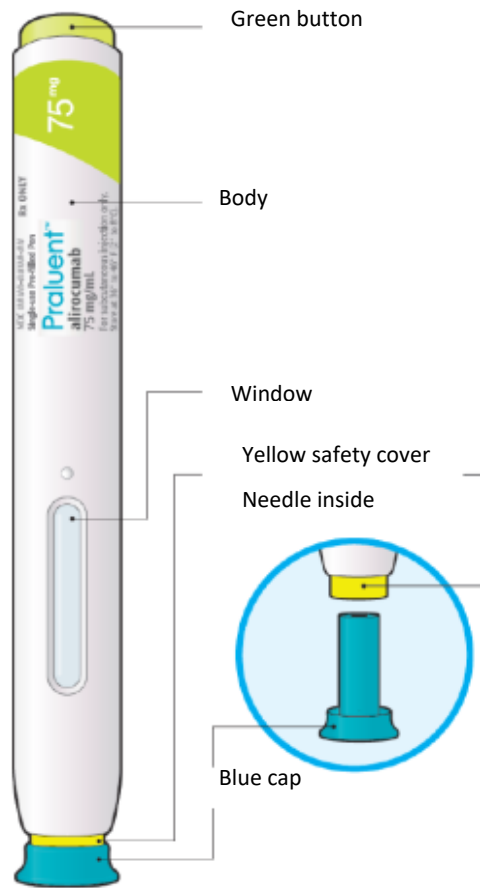
IMPORTANT INFORMATION

- The device 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	Do not
<ul style="list-style-type: none">• 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 36°F to 46°F (2°C to 8°C). For detailed storage conditions see separate Patient Medication Information leaflet for PRALUENT.	<ul style="list-style-type: none">• 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 patient leaflet.

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



For single use only

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).

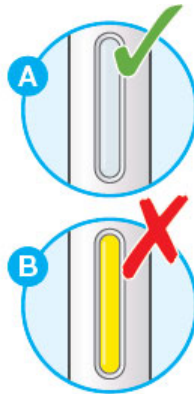
1. Look at the label on the pen.

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



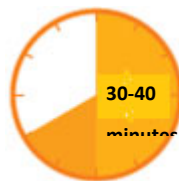
2. Look at the window.

- Check the liquid is clear, 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).
- Do not use this medicine if the solution is discolored or cloudy, or if it contains visible flakes or particles.



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

- This is important for administering the entire dose and helps minimize discomfort.
- Take PRALUENT out of the refrigerator to warm up before using.
- 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.

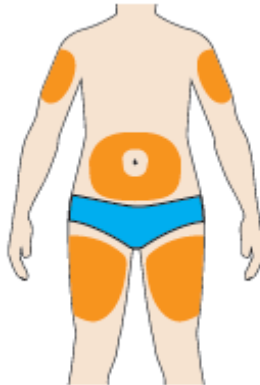


4. Prepare the injection site.

- Wash your hands with soap and water and dry with a towel.
- Clean skin in the injection area with an alcohol wipe.
- You can inject into your (see below picture):
 - thigh
 - belly (except for the 5 cm/2 inch area around your navel)
 - upper arm
- You can stand or sit to give yourself an injection.

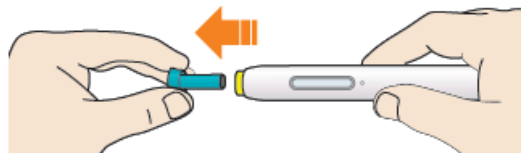
Important:

- Change (rotate) your injection site each time you give yourself an injection. If you need to use the same injection area, make sure it is not the same spot on the site you used last time.
- Do not inject into areas where the skin is injured, tender, hard, red, or hot. Do not inject PRALUENT into areas with visible veins, scars or stretch marks



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.



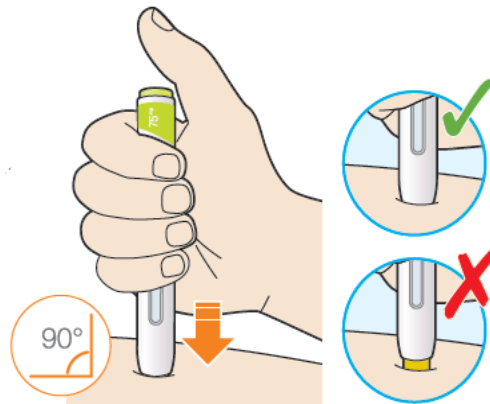
2. Hold the PRALUENT pen like this.

- 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.



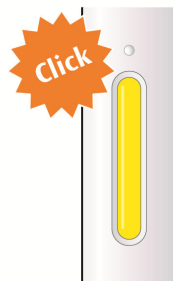
5. Keep holding the pen against your skin after releasing the button

- The injection may take up to 20 seconds.



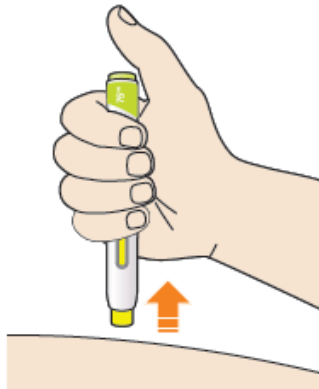
6. Check the window has turned yellow, before removing the pen.

- 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 1-800-265-7927 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.
- Throw away the pen in a puncture-resistant container immediately after they have been used
- Dispose of used container according to your local regulations.
- Always keep the container out of the reach of children.



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

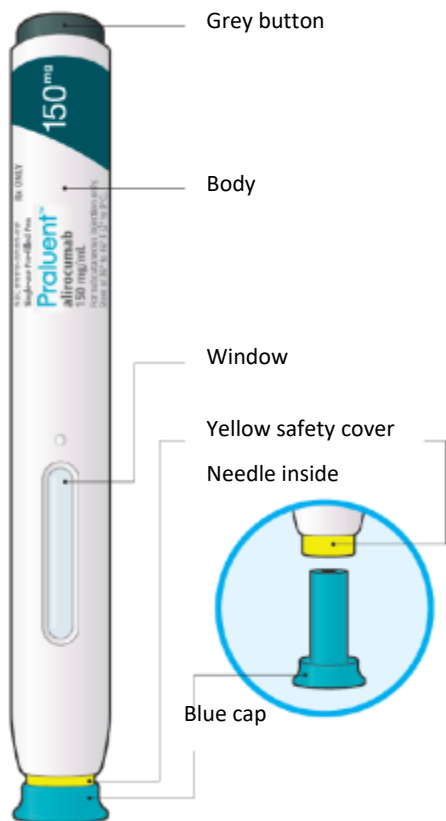
IMPORTANT INFORMATION

- The device 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	Do not
<ul style="list-style-type: none">• 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 36°F to 46°F (2°C to 8°C). For detailed storage conditions see separate Patient Medications Information leaflet for PRALUENT.	<ul style="list-style-type: none">• 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 patient leaflet.

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



For single use only

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).

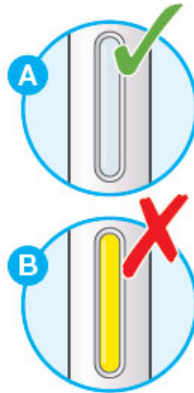
1. Look at the label on the pen.

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



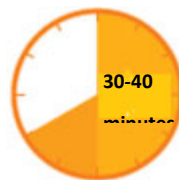
2. Look at the window.

- Check the liquid is clear, 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).
- Do not use this medicine if the solution is discolored or cloudy, or if it contains visible flakes or particles.



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

- This is important for administering the entire dose and helps minimize discomfort.
- Take PRALUENT out of the refrigerator to warm up before using.
- 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.



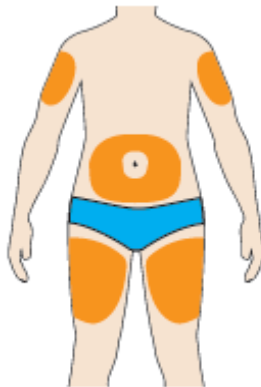
4. Prepare the injection site.

- Wash your hands with soap and water and dry with a towel.
- Clean skin in the injection area with an alcohol wipe.
- You can inject into your (see below picture):

- thigh
- belly (except for the 5 cm/2 inch area around your navel)
- upper arm
- You can stand or sit to give yourself an injection.

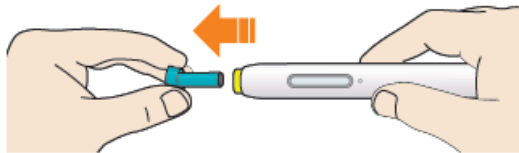
Important:

- Change (rotate) your injection site each time you give yourself an injection. If you need to use the same injection area, make sure it is not the same spot on the site you used last time.
- Do not inject into areas where the skin is injured, tender, hard, red, or hot. Do not inject PRALUENT into areas with visible veins, scars or stretch marks.



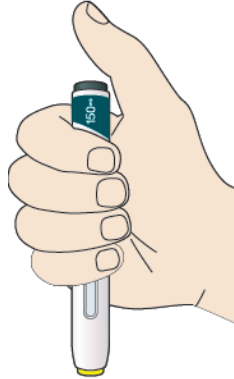
STEP B: HOW TO INJECT

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.



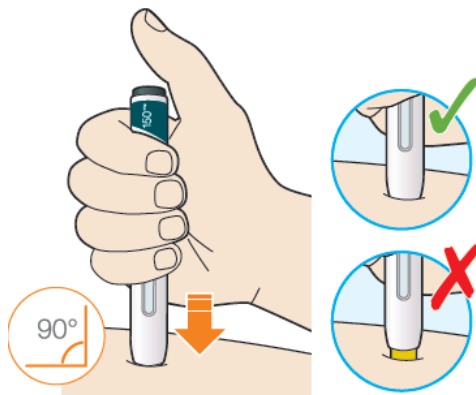
2. Hold the PRALUENT pen like this.

- 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.



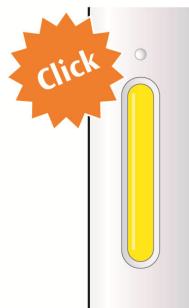
5. Keep holding the pen against your skin after releasing the button

- The injection may take up to 20 seconds.



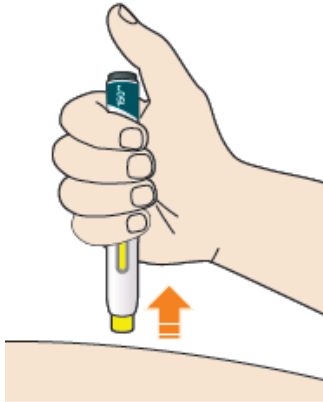
6. Check the window has turned yellow, before removing the pen.

- 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 1-800-265-7927 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.
- Throw away the pen in a puncture-resistant container immediately after they have been used
- Dispose of used container according to your local regulations.
- Always keep the container out of the reach of children.

