

Instructions for use for the Aranesp (SureClick) pre-filled pen

It is important that you do not try to give the injection unless you or your caregiver has received training from your healthcare provider.

There are additional educational materials available to train you on how to self administer Aranesp pre-filled pen, a dummy demonstration device and this booklet for use for patients/ caregivers with diminished eyesight.

This material is intended for patients with diminished eyesight

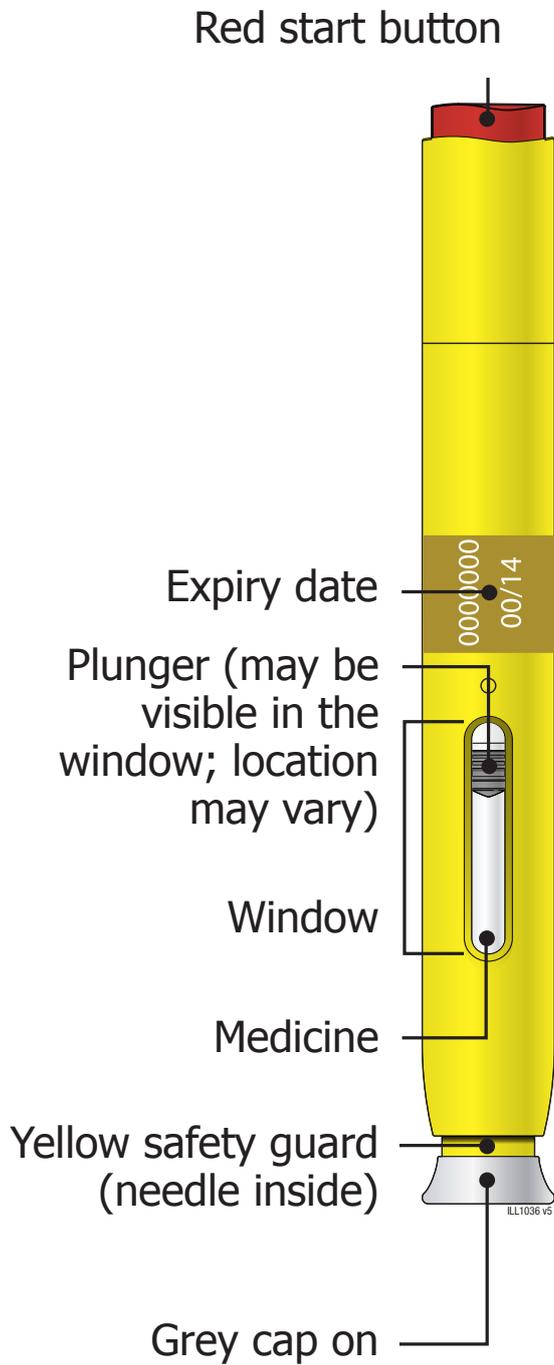
Reporting of side effects and quality defects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. Side effects can be reported directly to the Health Products Regulatory Authority (HPRA) using the available methods via www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine. Side effects should also be reported to Amgen Limited on +44 (0) 1223 436441 or Freephone 1800 535 160.

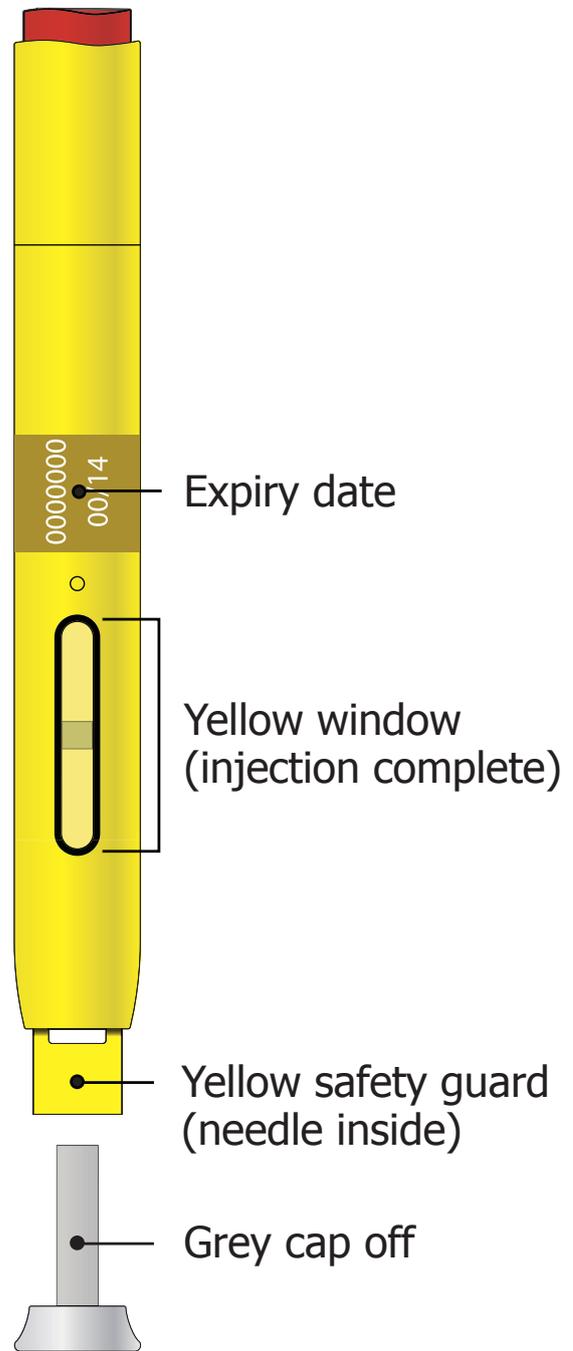
Please report any potential quality issue with the Amgen product you have received, by calling us on +44 (0) 1223 436441 or Freephone 1800 535 160 and providing us with the details. Please ensure that you keep your packaging, so we are able to identify your product more easily.

Guide to parts

Before use



After use



Important: Needle is inside the yellow safety guard.

Important

Before you use the Aranesp SureClick pre-filled pen, read this important information:

Storing your Aranesp SureClick pre-filled pens

- Keep the pre-filled pen and all medicines out of the sight and reach of children.
 - Keep the pre-filled pen in the outer carton in order to protect from light or physical damage.
 - Store the pre-filled pen in the refrigerator (2°C – 8°C).
 - Once your pre-filled pen has been removed from the refrigerator, and left at room temperature (up to 25°C) for approximately 30 minutes before injection, it must either be used within seven days or disposed of.
- ✗ Do not** store the pre-filled pen in extreme heat or cold. For example, avoid storing in your car glove box or boot.
- ✗ Do not** freeze. Do not use Aranesp if you think it has been frozen.

Using your Aranesp SureClick pre-filled pens

- Your healthcare provider has prescribed the Aranesp pre-filled pen for injection into the tissue just under the skin (subcutaneous use).
- ✗ Do not** use the pre-filled pen after the expiry date on the label. The expiry date refers to the last day of that month.
- ✗ Do not** shake the pre-filled pen.
- ✗ Do not** remove the grey cap from the pre-filled pen until you are ready to inject.
- ✗ Do not** use the pre-filled pen if it has been dropped on a hard surface. Part of the pre-filled pen may be broken even if you cannot see the break. Use a new pre-filled pen.
- The grey cap on the pen contains dry natural rubber, which is made from latex. Tell your healthcare provider if you are allergic to latex.

For more information or help, contact your healthcare provider.

Step 1: Prepare

A

Remove one pre-filled pen from the carton.

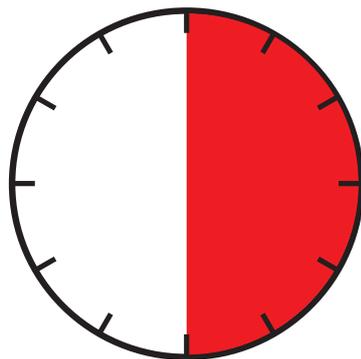
Carefully lift the pre-filled pen straight up out of the carton.

Put the original carton with any unused pre-filled pens back in the refrigerator.

Leave the pre-filled pen at room temperature for at least 30 minutes before injecting.

- ✗ **Do not** put the pre-filled pen back in the refrigerator once it has reached room temperature.
- ✗ **Do not** try to warm the pre-filled pen by using a heat source such as hot water or microwave.
- ✗ **Do not** leave the pre-filled pen in direct sunlight.
- ✗ **Do not** shake the pre-filled pen.
- ✗ **Do not** remove the grey cap from the pre-filled pen yet.

30 minutes

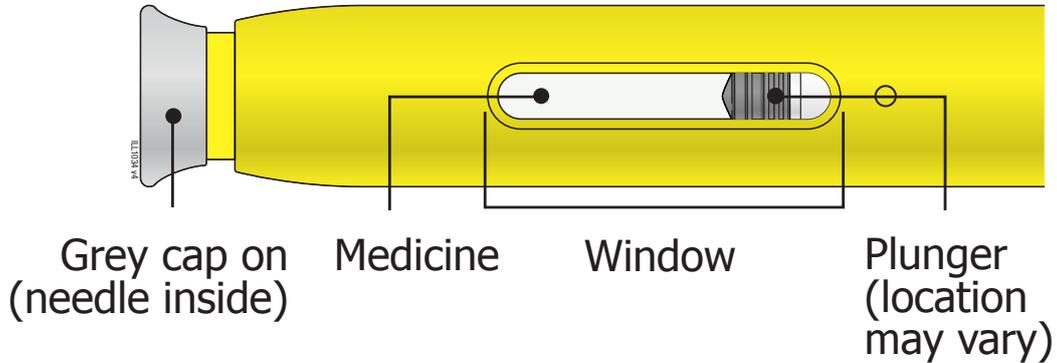


Step 1: Prepare continues

Step 1: Prepare

B

Inspect the pre-filled pen.



Make sure the medicine in the window is a clear and colourless liquid.

- Check that it is the correct dose that your healthcare provider has prescribed.
- **You may see the plunger in the inspection window at a different location, depending upon the strength.**

- ✗ **Do not** use the pre-filled pen if the medicine is cloudy or discoloured or contains flakes or particles.
- ✗ **Do not** use the pre-filled pen if any part appears cracked or broken.
- ✗ **Do not** use the pre-filled pen if the grey cap is missing or not securely attached.
- ✗ **Do not** use the pre-filled pen if the expiry date printed after EXP on the label has passed.

In all cases, use a new pre-filled pen and contact your healthcare provider.

Step 1: Prepare *continues*

Step 1: Prepare

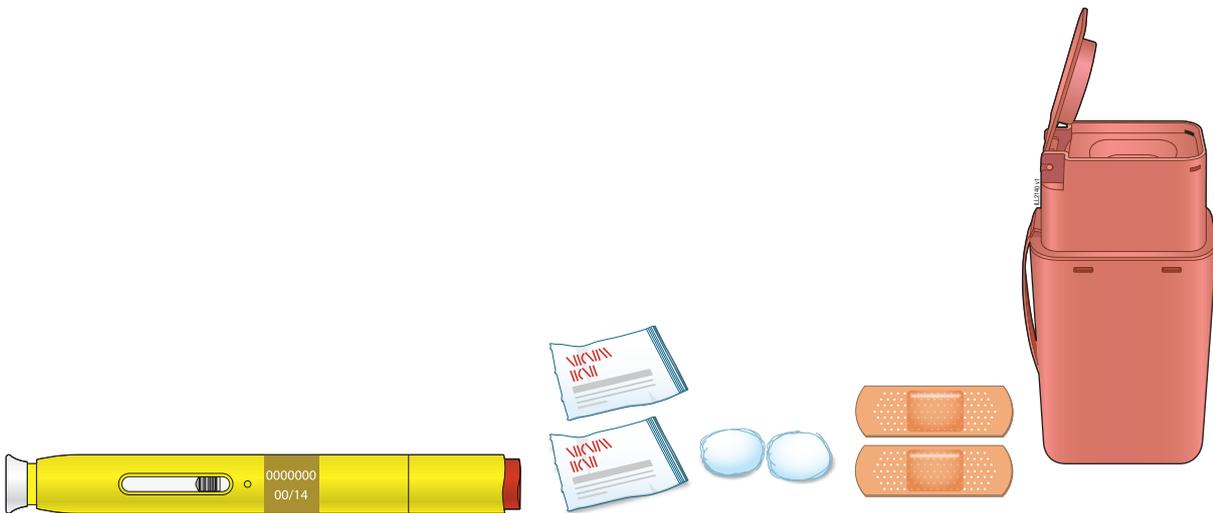
C

Gather all the materials needed for your injection.

Wash your hands thoroughly with soap and water.

On a clean, well-lit work surface, place the:

- New pre-filled pen
- Alcohol wipes
- Cotton ball or gauze pad
- Plaster
- Sharps disposal container



Step 1: Prepare *continues*

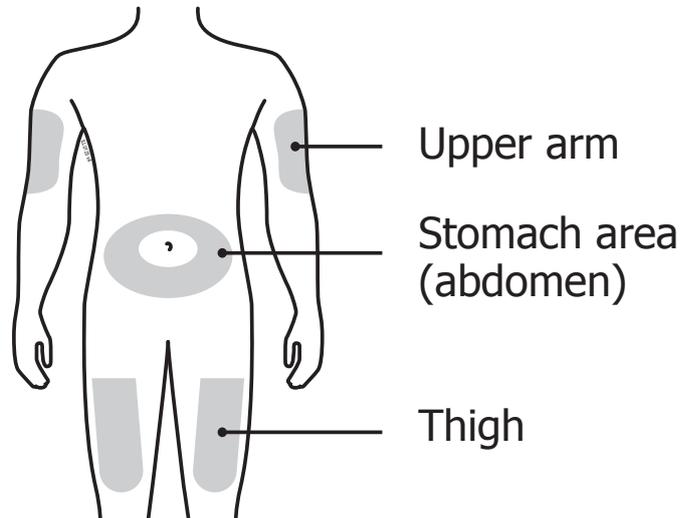
Step 1: Prepare

D

Prepare and clean your injection site.

You can use:

- Your thigh
- Your stomach area (abdomen), except for a 5 cm (2-inch) area right around your navel
- The outer area of upper arm (only if someone else is giving you the injection)



Clean the injection site with an alcohol wipe. Let your skin dry.

X Do not touch this area again before injecting.

- Choose a different site each time you give yourself an injection. If you want to use the same injection site, make sure it is not the same spot on the injection site you used for a previous injection.

X Do not inject into areas where the skin is tender, bruised, red, or hard.

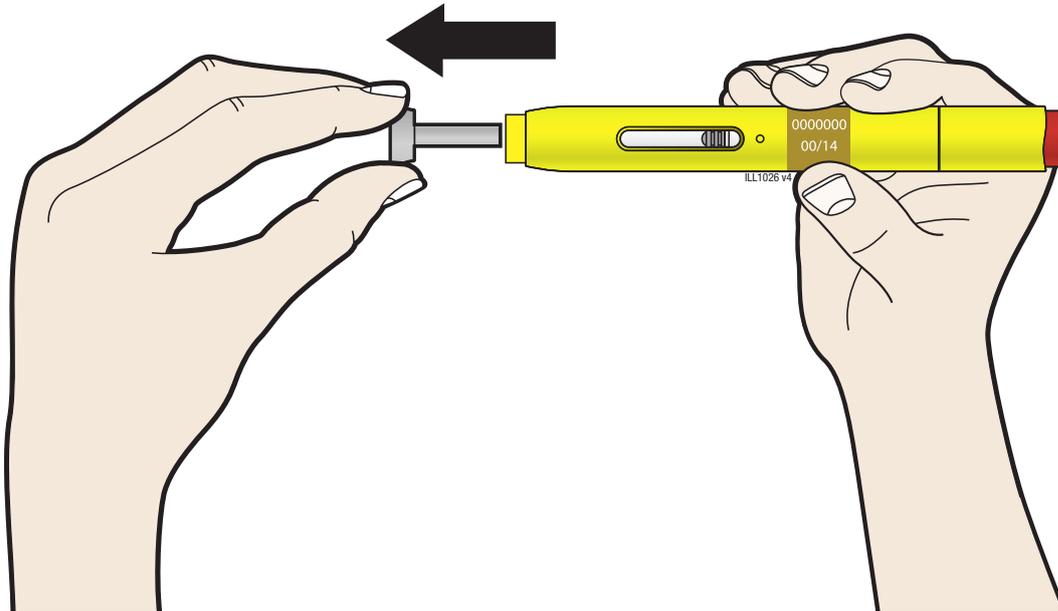
- Avoid injecting into raised, thick, red, or scaly skin patches or lesions, or areas with scars or stretch marks.

Important: Follow your healthcare provider's instructions about selecting sites for injection appropriate to you and about changing the site for each injection.

Step 2: Get ready

E

Pull the grey cap straight off, only when you are ready to inject. **Do not** leave the grey cap off for more than five minutes. This can dry out the medicine.



It is normal to see a drop of liquid at the end of the needle or yellow safety guard.

- ✘ **Do not** twist or bend the grey cap.
- ✘ **Do not** put the grey cap back onto the pre-filled pen.
- ✘ **Do not** remove the grey cap from the pre-filled pen until you are ready to inject.

If you are unable to inject, please contact your healthcare provider immediately.

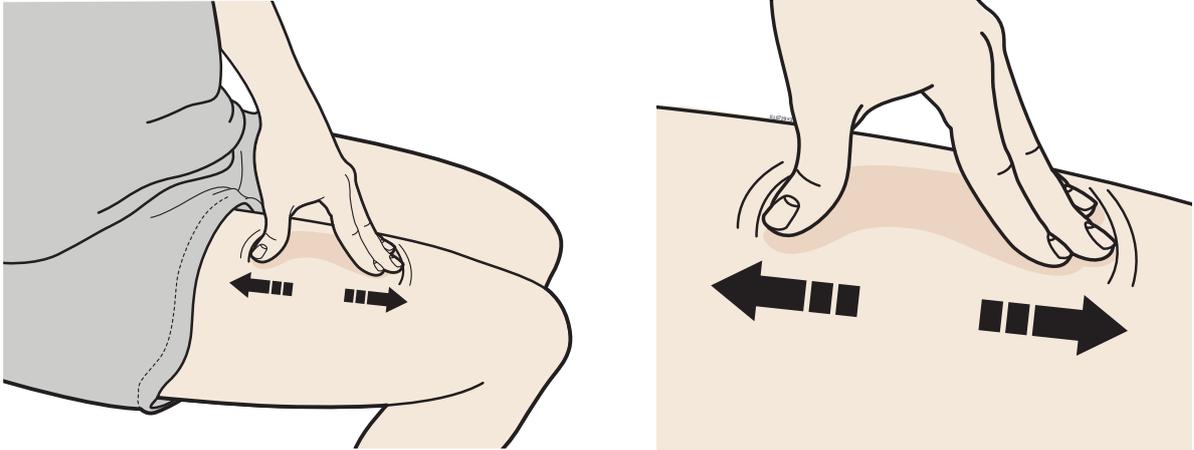
Step 2: Get ready *continues*

Step 2: Get ready

F

Stretch or pinch your injection site to create a firm surface.

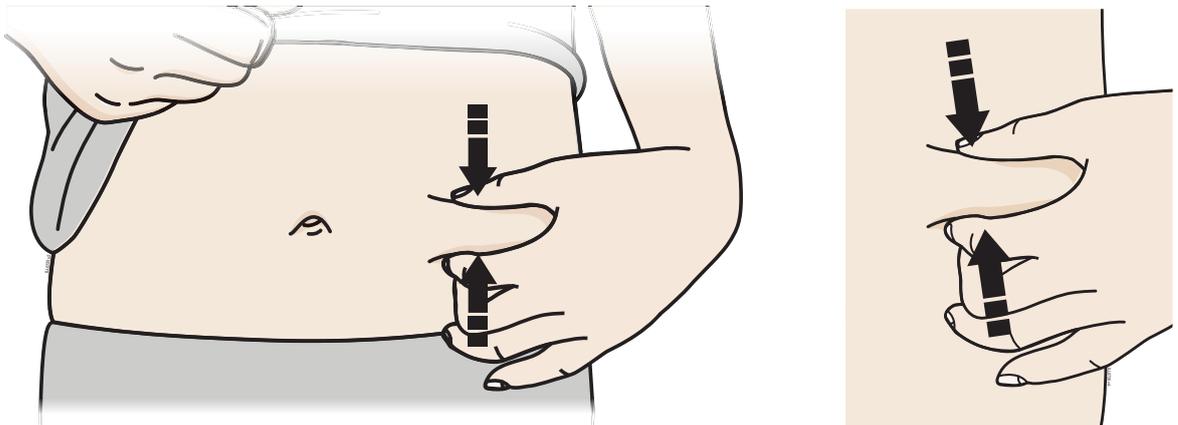
Stretch method



Stretch your skin firmly by moving your thumb and fingers in opposite directions, creating an area about **5 cm (2-inches)** wide.

OR

Pinch method



Pinch your skin firmly between your thumb and fingers, creating an area about **5 cm (2-inches)** wide.

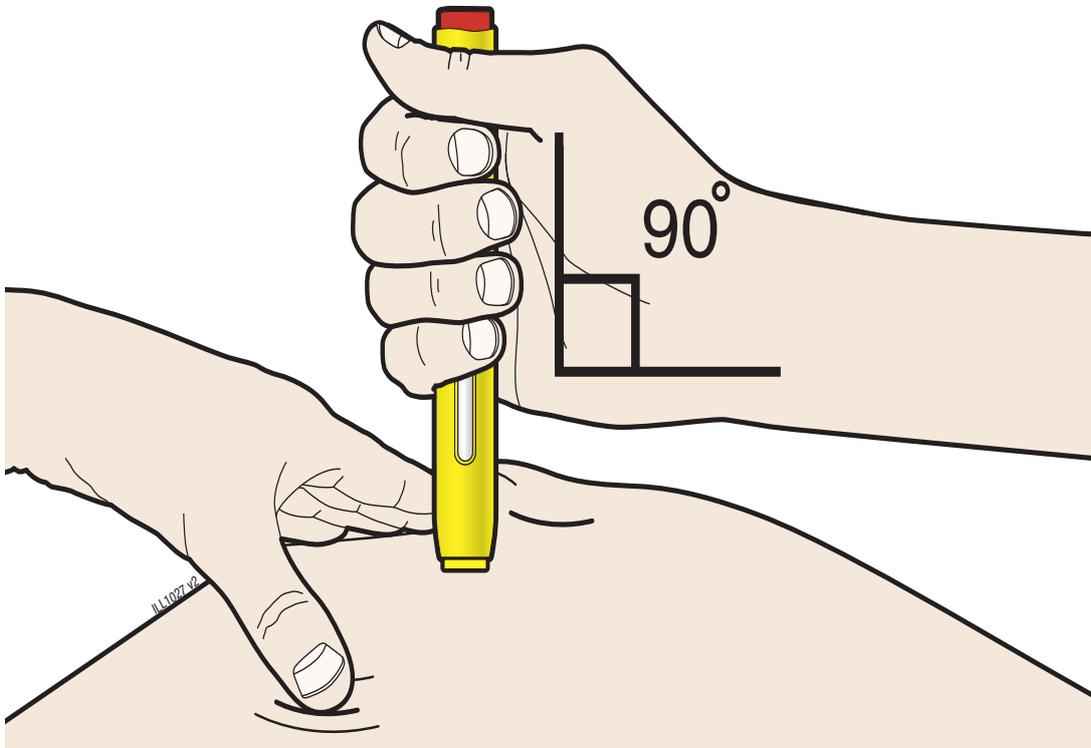
Important: It is important to keep your skin stretched or pinched while injecting.

Step 3: Inject

Please open out the folded pages before you start "Step 3: Inject"

G

Keep stretching or pinching your skin. With the grey cap off, **place** the pre-filled pen on your skin at 90 degrees.



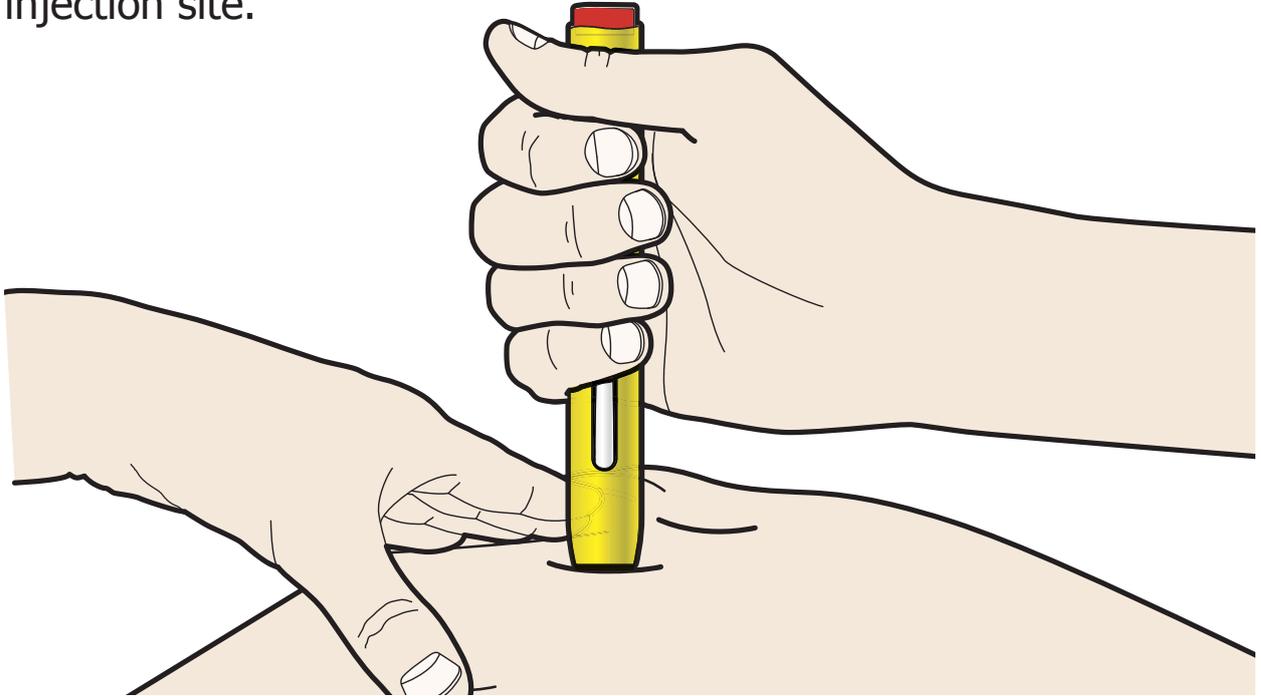
Important: Do not touch the red start button yet.

Step 3: Inject continues

Step 3: Inject

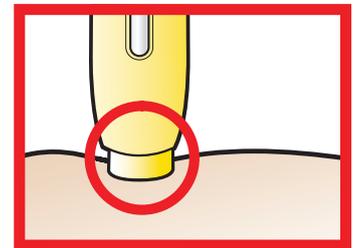
H

Firmly **push** the pre-filled pen down onto your skin until it stops moving. The safety guard retracts when pushed onto a firm injection site.

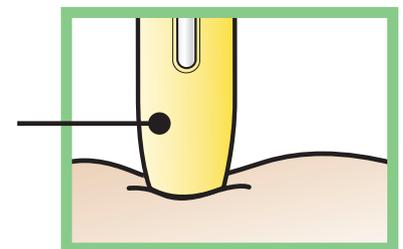


Important:

You must push the pre-filled pen all the way down but do not touch the red start button until you are ready to inject.



Yellow safety guard retracted



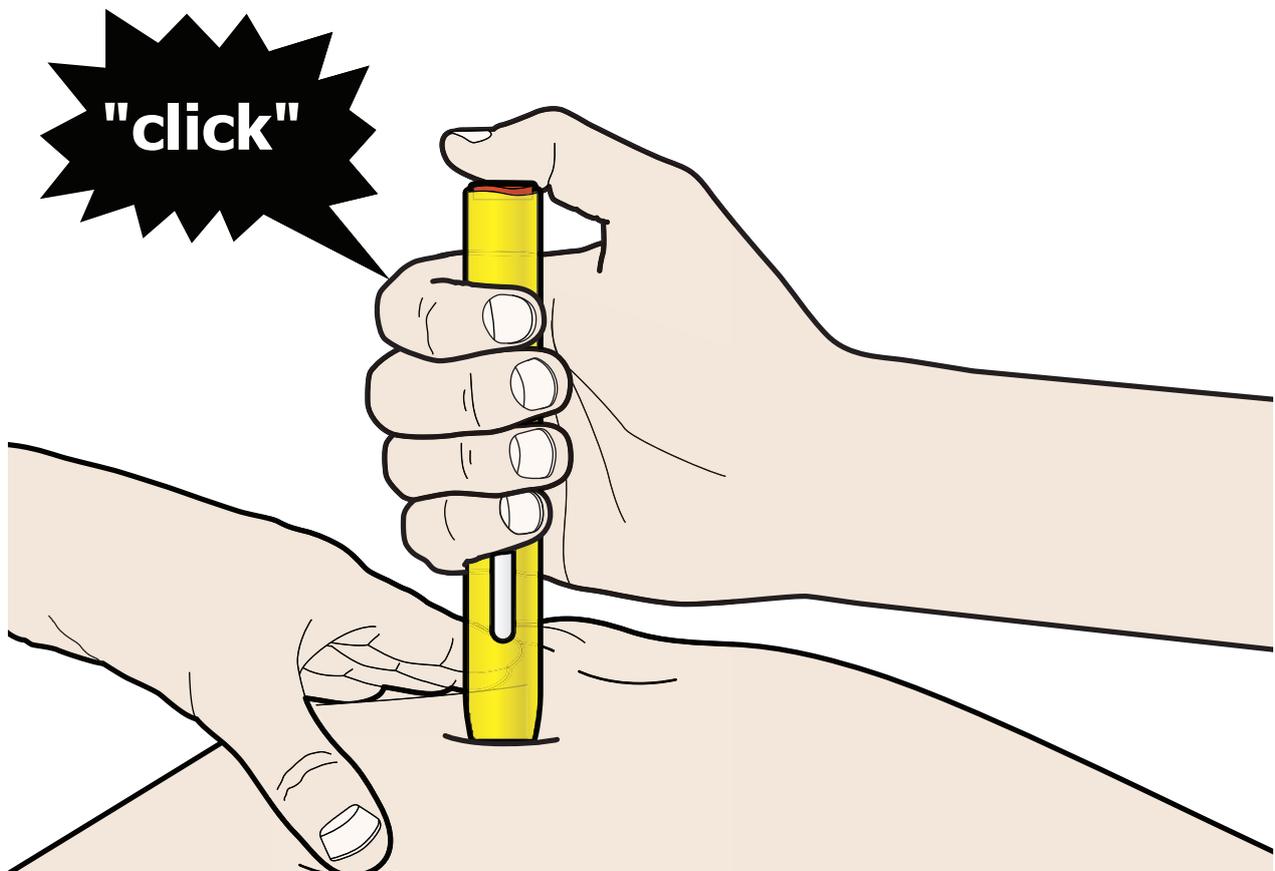
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Step 3: Inject continues

Step 3: Inject

I

When you are ready to inject, **press** the red start button.

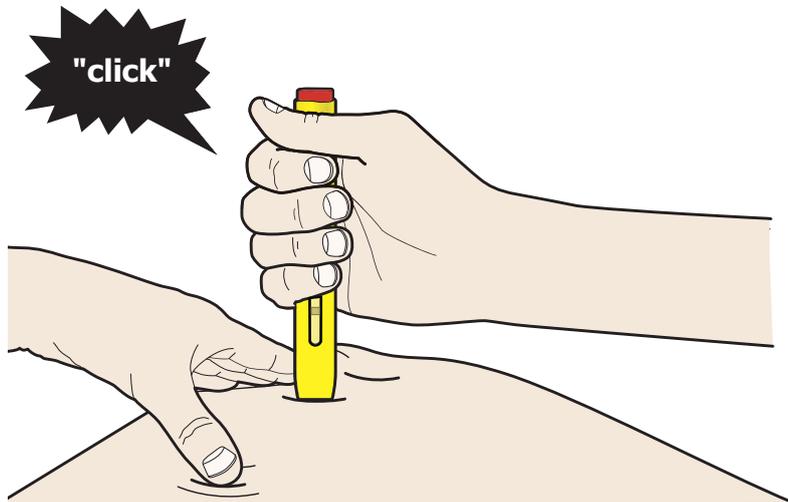


Step 3: Inject *continues*

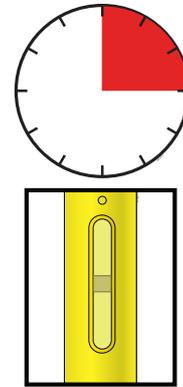
Step 3: Inject

J

Keep **pushing** the pre-filled pen down on your skin. Your injection could take about **15** seconds.

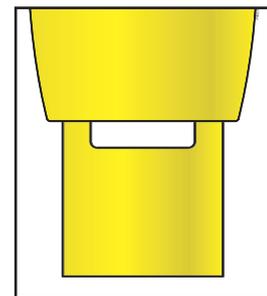


15 seconds



Window turns yellow when the injection is done

Note: After you remove the pre-filled pen from your skin, the needle will be automatically covered.



Important: When you remove the pre-filled pen, if the window has not turned yellow, or if it looks like the medicine is still injecting, this means you have not received a full dose. Contact your healthcare provider immediately.

K

Examine the injection site.

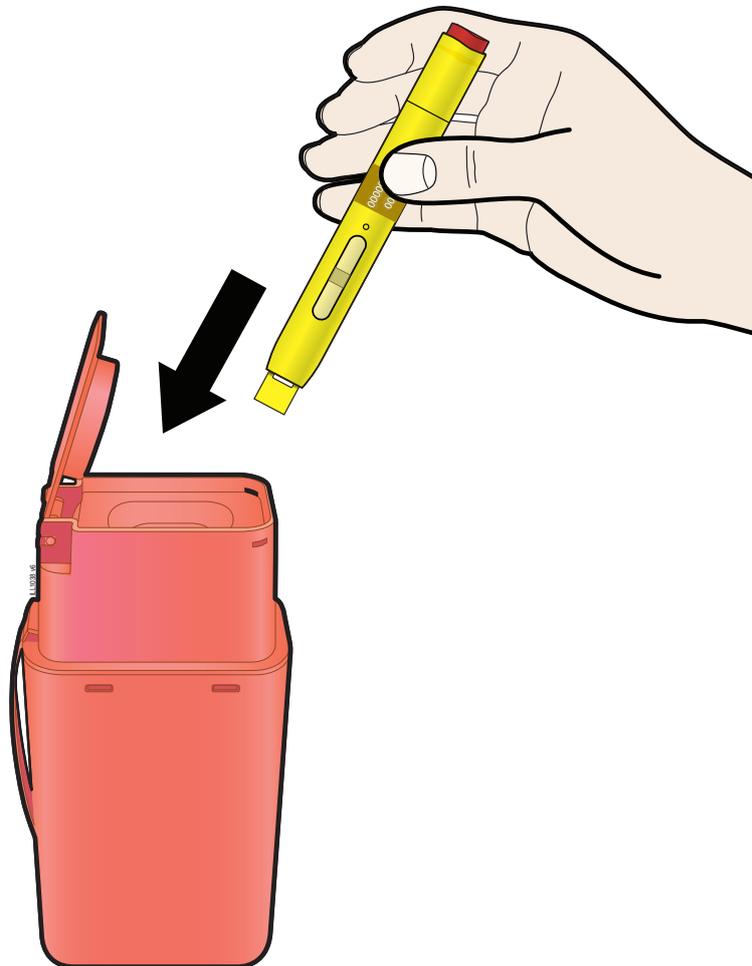
- If there is blood, press a cotton ball or gauze pad on your injection site.

Do not rub the injection site. Apply a plaster if needed.

Step 4: Finish

L

Dispose of the used pre-filled pen and grey cap.



Put the used pre-filled pen in the sharps disposal container immediately after use.

- X Do not** reuse the pre-filled pen.
- X Do not** recycle the pre-filled pen or sharps disposal container or throw them into household rubbish.

Talk with your healthcare provider about proper disposal. There may be local guidelines for disposal.

Important: Always keep the sharps disposal container out of the sight and reach of children.

