

INSTRUCTIONS FOR USE

AMGEVITA® solution for injection is supplied as a single-use pre-filled syringe with a SureClick® automatic injection device (“pen”). Consult your healthcare provider if you have any questions about your dose.

Your healthcare provider has prescribed AMGEVITA SureClick pen for your injections. If your healthcare provider decides that you or a caregiver can give your injections of AMGEVITA at home, you should receive training on the right way to prepare and inject AMGEVITA. Do not try to inject yourself until you have been shown the right way to give the injections by your healthcare provider.

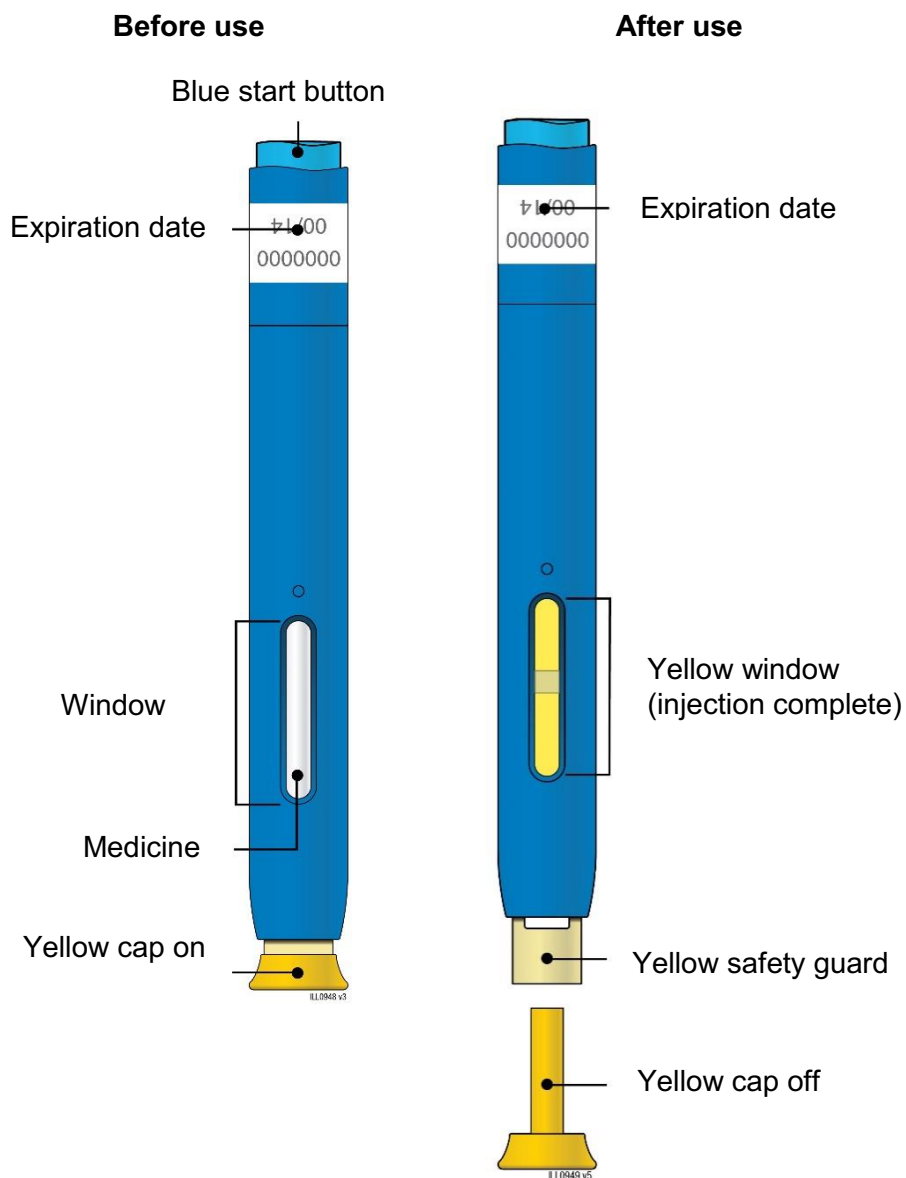
Please read all of the instructions before using AMGEVITA SureClick pre-filled pen. Call your healthcare provider if you or your caregiver have any questions about the right way to inject AMGEVITA.

INSTRUCTIONS FOR USE

AMGEVITA® (adalimumab)

Solution for injection, single use pre-filled SureClick® pen For subcutaneous use

Guide to parts



Important: Needle is inside the yellow safety guard

IMPORTANT

**Before you use an AMGEVITA SureClick pre-filled pen, read this important information:
Storing your AMGEVITA SureClick pre-filled pens**

- Keep the AMGEVITA SureClick pre-filled pen out of the sight and reach of children.
- Keep the AMGEVITA SureClick pre-filled pen in the original carton in order to protect from light or physical damage.
- The AMGEVITA SureClick pre-filled pen should be stored in the refrigerator (2°C – 8°C).
- If needed, you may store the AMGEVITA SureClick pre-filled pen at room temperature at up to 25°C for up to 14 days. Record the date you start doing this, to make sure you do not keep it out of the refrigerator for longer than 14 days.

You can use the table below to help you to remember the dates.

	Date pen first stored at room temperature (up to 25°C)	USE BY OR DISCARD DATE (if pen not used within 14 days at up to 25°C)
Pen 1		
Pen 2		

- Throw away AMGEVITA SureClick that has been stored at room temperature after 14 days.
- **Do not** store the AMGEVITA SureClick pre-filled pen in extreme heat or cold. For example, avoid storing in your vehicle's glove box or boot.
- **Do not** freeze the AMGEVITA SureClick pre-filled pen.

Using your AMGEVITA 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.
- **Do not** use the AMGEVITA SureClick pre-filled pen after the expiration date on the label.
- **Do not** shake the AMGEVITA SureClick pre-filled pen.
- **Do not** remove the yellow cap from the AMGEVITA SureClick pre-filled pen until you are ready to inject.
- **Do not** use the AMGEVITA SureClick pre-filled pen if it has been frozen.
- **Do not** use an AMGEVITA SureClick pre-filled pen if it has been dropped on a hard surface. Part of the AMGEVITA SureClick pre-filled pen may be broken even if you cannot see the break. Use a new AMGEVITA SureClick pre-filled pen and contact your healthcare provider.
- This product contains dry natural rubber, which is made from latex, within the yellow cap. Tell your healthcare provider if you are allergic to latex.

For more information or help call AMGEN Medical Information on 1800 803 638. If required, you will be advised to contact your healthcare provider.

Step 1: Prepare

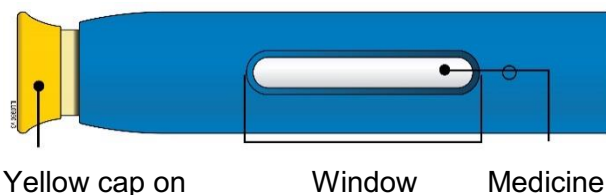
A. Remove one AMGEVITA SureClick pre-filled pen from the package.
Carefully lift the pre-filled pen straight up out of the box.

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

For a more comfortable injection, leave the pre-filled pen at room temperature for **15 to 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 yellow cap from the pre-filled pen yet.

B. Inspect the AMGEVITA SureClick pre-filled pen.



Make sure the medicine in the window is clear and colourless to slightly yellow.

- **Do not** use the pre-filled pen if:
 - The medicine is cloudy or discoloured or contains flakes or particles.
 - Any part appears cracked or broken.
 - The pre-filled pen has been dropped.
 - The yellow cap is missing or not securely attached.
 - The expiration date printed on the label has passed.

In all cases, call Amgen Information on 1800 803 638. If required, you will be advised to contact your healthcare provider and use a new pre-filled pen.

C. Gather all materials needed for your injection.

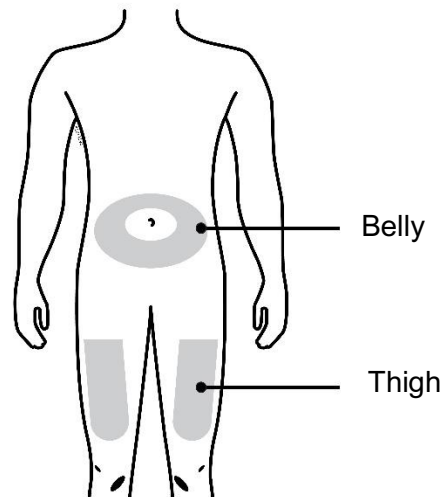
Wash your hands thoroughly with soap and water.

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

- New pre-filled pen
 - Alcohol wipes
 - Cotton ball or gauze pad
 - Adhesive bandage
 - Sharps disposal container
- Yellow Australian standard sharps containers can be bought from a pharmacy.



D. Prepare and clean your injection site.



You can use:

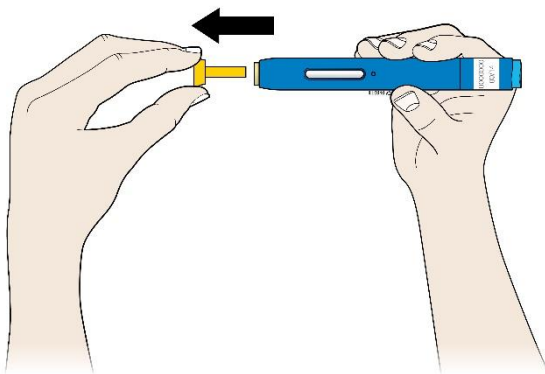
- Your thigh
- Stomach area (abdomen), except for a 5 centimetre (2 inch) area around your navel (belly button).

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

- **Do not** touch this area again before injecting.
- Choose a different site each time you give yourself an injection. If you need to use the same injection site, make sure it is not the same spot on the injection site you used for a previous injection.
 - **Do not** inject into areas where the skin is tender, bruised, red, or hard. Avoid injecting into areas with scars or stretch marks.
- If you have psoriasis, you should avoid injecting directly into raised, thick, red, or scaly skin patch or lesion.

Step 2: Get ready

E. Pull the yellow cap straight off when you are ready to inject.



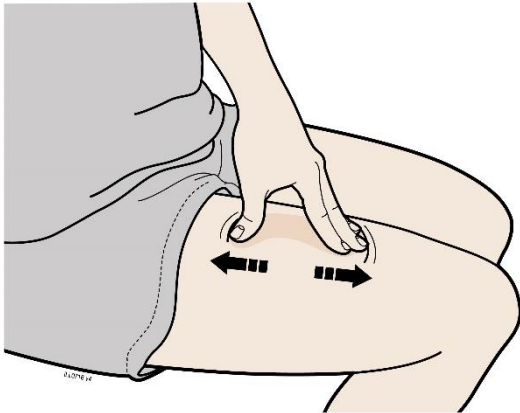
It is normal to see a drop of liquid at the end of the needle or yellow safety guard.

- **Do not** twist or bend the yellow cap.
- **Do not** put the yellow cap back onto the pre-filled pen.

- **Do not** remove the yellow cap from the pre-filled pen until you are ready to inject.
Important: Throw the yellow cap into the sharps disposal container.

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

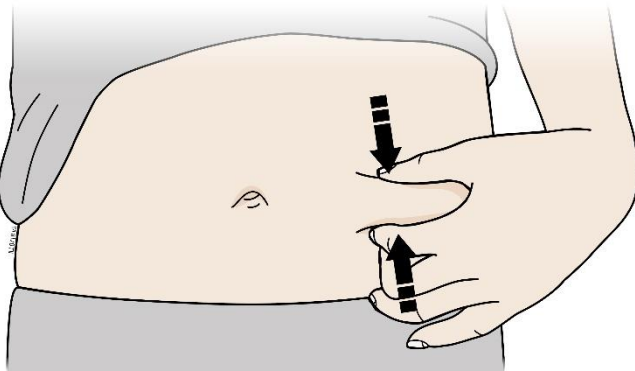
Stretch method



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

OR

Pinch method

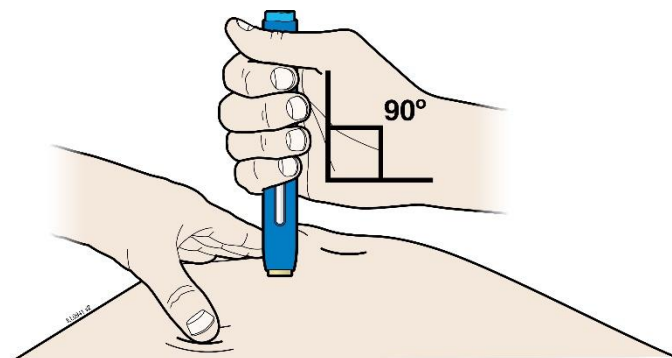


Pinch the skin firmly between your thumb and fingers, creating an area about 5 centimetres (2 inches) wide.

Important: Keep the skin stretched or pinched while injecting.

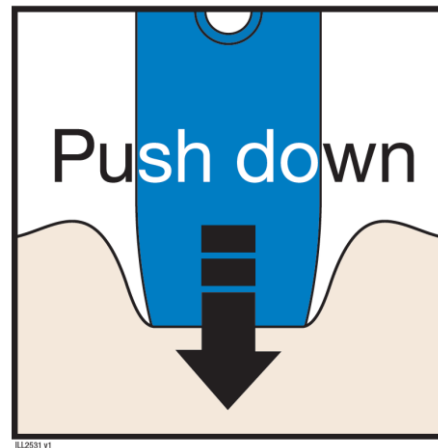
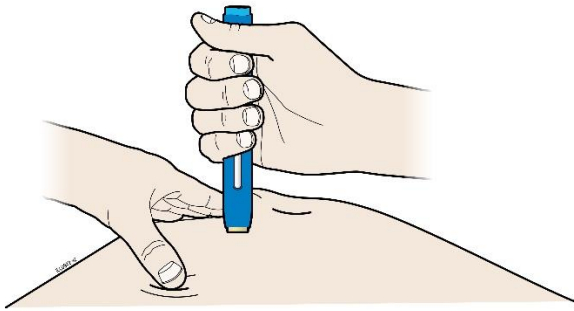
Step 3: Inject

- G. Hold the stretch or pinch. With the yellow cap off, **place** the pre-filled pen on your skin at 90 degrees. Make sure the window is visible when you are placing the pre-filled pen against the skin.



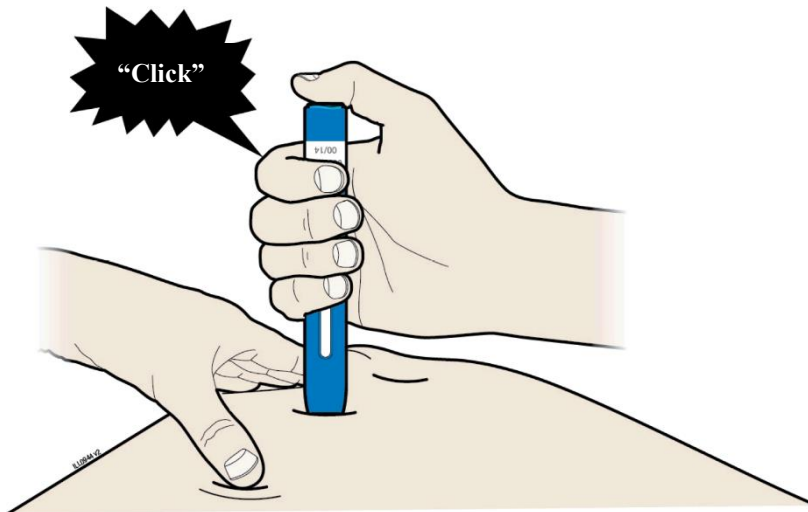
Important: Do not touch the blue start button yet.

- H. Firmly **push** the pre-filled pen down onto the skin until it stops moving.

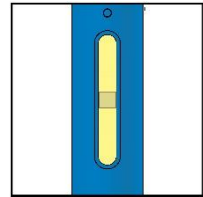
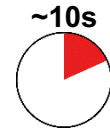
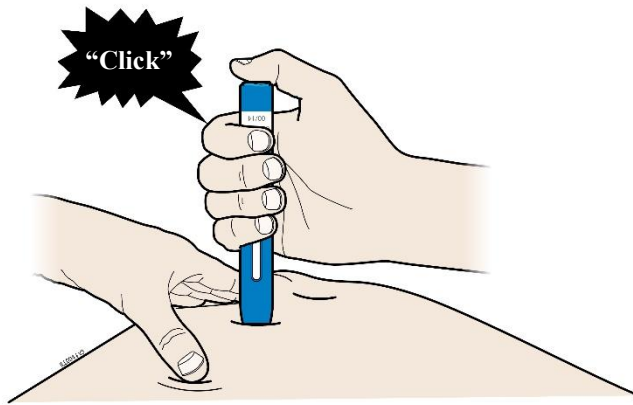


Important: You must push the yellow safety guard all the way down against your skin to unlock the activation mechanism but do not touch the blue start button until you are ready to inject.

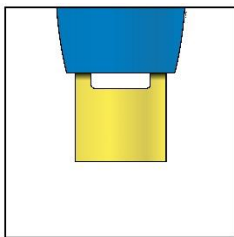
- I. When you are ready to inject, **press** the blue start button.



- J. Keep **pushing** down on your skin. Your injection could take about 10 seconds.



The 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. Call your healthcare provider immediately.

Step 4: Finish

K. Discard the used pre-filled pen and the yellow cap.



- Put the used SureClick pre-filled pen in a sharps disposal container immediately after use. **Do not** throw away (dispose of) the SureClick pre-filled pen in your household waste.
- If you do not have a sharps disposal container, you may use a household container that:
 - Is made of a heavy-duty plastic;
 - Can be closed and has a tight-fitting, puncture-resistant lid, without sharp objects being able to come out;
 - Upright and stable during use;
 - Leak-resistant and
 - Properly labelled to warn of hazardous waste inside the container.
- When your sharps disposal container is almost full, you will need to follow your local council guidelines for the right way to dispose of your sharps disposal container. There may be state or local council laws about how you should throw away used needles and syringes. For more information about safe sharps disposal, talk with your healthcare provider about proper disposal.
- **Do not** reuse the pre-filled pen.
- **Do not** recycle the pre-filled pen or sharps disposal container or throw them into the household waste.

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

L. 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 an adhesive bandage if needed.

Please also read:

- the Product Information leaflet in the AMGEVITA package, and
- the AMGEVITA Consumer Medicine Information, which is available from your pharmacist or on line at <https://www.ebs.tga.gov.au/> (under TGA Public Information section).

Some commonly asked questions about AMGEVITA SureClick pre-filled pen

What happens if I press the blue start button before I am ready to do the injection on my skin?

Even when you press the blue start button, the injection will only happen when the yellow safety guard is also pushed into the prefilled pen.

Can I move the AMGEVITA SureClick prefilled pen around on my skin while I am choosing an injection site?

It is okay to move the AMGEVITA SureClick prefilled pen around on the injection site as long as you **do not** press the blue start button. However, if you press the blue start button and the yellow safety guard is pushed into the pre-filled pen, the injection will begin.

Can I release the blue start button after I start my AMGEVITA injection?

You can release the blue start button but continue to hold the pre-filled pen firmly against your skin during the injection.

Will the blue start button pop up after I release my thumb?

The blue start button may not pop up after you release your thumb if you held your thumb down during the injection. This is okay.

What if I did not hear a click after pushing the AMGEVITA SureClick pre-filled pen down on my skin for 10 seconds?






If you did not hear a click, you can confirm a complete injection by checking that the window has turned yellow.

Who do I contact if I need help with the AMGEVITA SureClick pre-filled pen or my AMGEVITA injection?

If you have any questions about the AMGEVITA SureClick pre-filled pen, its storage, or about your injection, call AMGEN Medical Information on telephone number 1800 803 638 for help. If required, you will be advised to contact your healthcare provider.

AMGEVITA® is a registered trademark of Amgen.

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Ph: 1800 803 638
www.amgenmedinfo.com.au

SYMBOL TABLE				
 40 mg/0.8 mL Prefilled Autoinjector	 This Product Contains Dry Natural Rubber	 Single Use	 CAUTION, Consult Accompanying Documents	 Lot Number

Date of last amendment: 11 November 2021

Version 3.0