

INSTRUCTIONS FOR USE

AMGEVITA® solution for injection is supplied as a single-use pre-filled syringe. Consult your healthcare provider if you have any questions about your dose.

Your healthcare provider has prescribed AMGEVITA for your injections. If your healthcare provider decides that you or a caregiver may be able to 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 pre-filled syringe.
Call your healthcare provider if you or your caregiver have any questions about the right way to inject AMGEVITA.

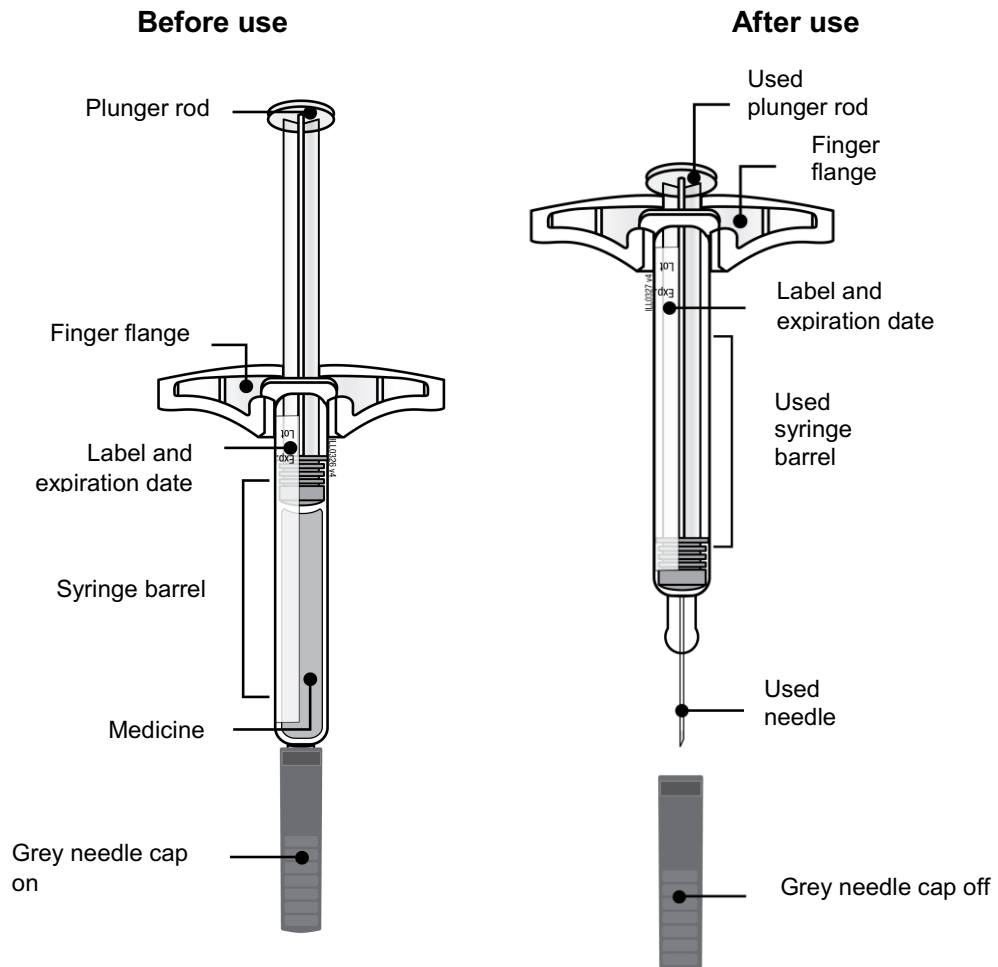
INSTRUCTIONS FOR USE

AMGEVITA® (adalimumab)

Solution for injection, single use pre-filled syringe

For subcutaneous use

Guide to parts



Important:

The needle is covered by the needle cap before use

Important

Before you use an AMGEVITA prefilled syringe, read this important information:

Storing your AMGEVITA pre-filled syringes

- Keep the AMGEVITA pre-filled syringe and all medicines out of the sight and reach of children.
- Keep the AMGEVITA pre-filled syringe in the original package to protect from light or physical damage.
- The AMGEVITA pre-filled syringe should be stored in the refrigerator (2°C to 8°C).
- If needed, you may store the AMGEVITA pre-filled syringe at room temperature (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 syringe first stored at room temperature (up to 25°C)	USE BY OR DISCARD DATE (if syringe not used within 14 days at up to 25°C)
Syringe 1		
Syringe 2		

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

Using your AMGEVITA pre-filled syringe

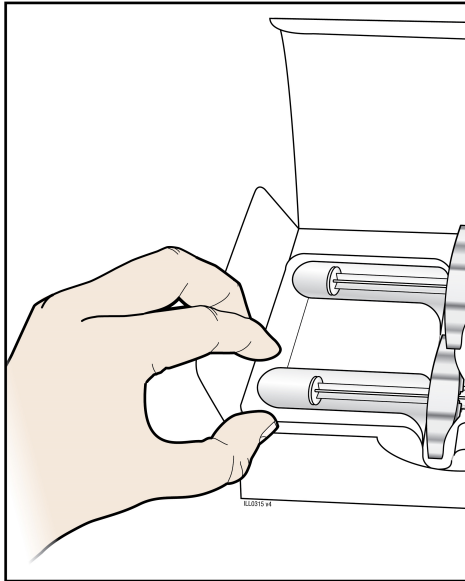
- It is important that you do not try to give the injection unless you or your caregiver has received training from your healthcare provider.
- **Do not** use an AMGEVITA pre-filled syringe after the expiration date on the label.
- **Do not** shake the AMGEVITA pre-filled syringe.
- **Do not** remove the needle cap from the AMGEVITA pre-filled syringe until you are ready to inject.
- **Do not** use the AMGEVITA pre-filled syringe if it has been frozen.
- **Do not** use an AMGEVITA pre-filled syringe if it has been dropped on a hard surface. Part of the AMGEVITA pre-filled syringe may be broken even if you cannot see the break. Use a new AMGEVITA pre-filled syringe and contact your healthcare provider.

The needle cover of the pre-filled syringe does not contain latex

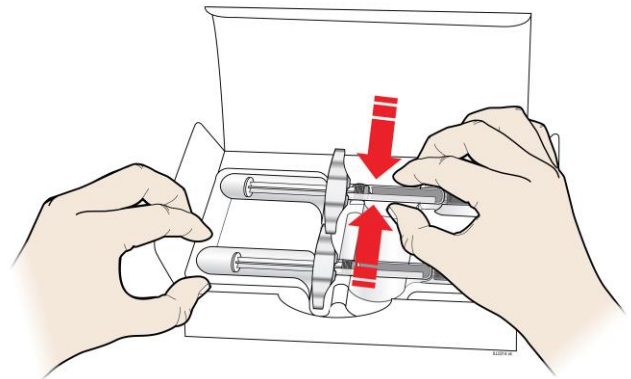
For more information or help call AMGEN Medical Information on 1800 803 638. If required, you will be advised to contact your healthcare provider.

Step 1: Prepare

- A. Remove the number of AMGEVITA pre-filled syringes you need from the package.
Grab the **syringe barrel** to remove the syringe from the tray.



Place your finger or thumb on edge of tray to secure it while you remove the syringe.



Grab Here

Put the original package with any unused syringes back in the refrigerator.

For safety reasons:

- **Do not** grab the plunger rod.
- **Do not** grasp the needle cap.
- **Do not** remove the needle cap until you are ready to inject.
- **Do not** remove the finger flange. This is part of the syringe.

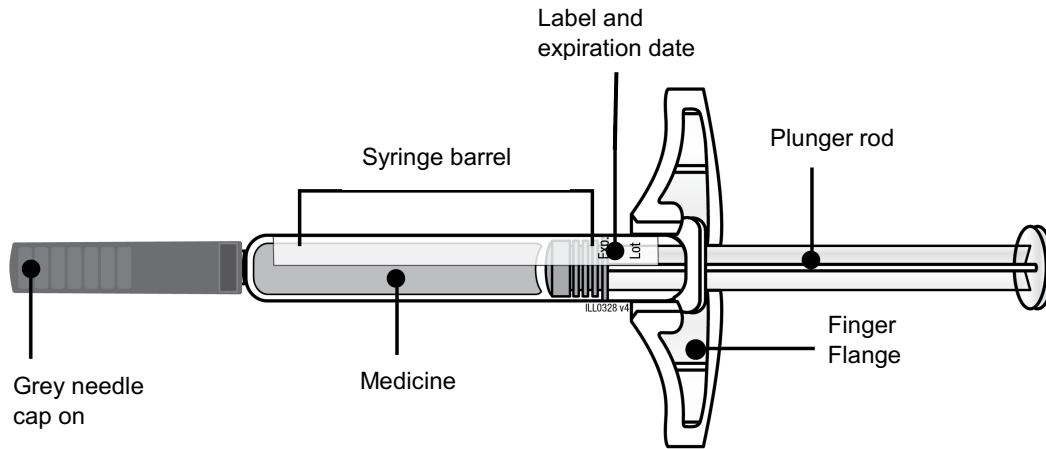
For a more comfortable injection, leave the syringe at room temperature for **15 to 30 minutes** before injecting.

- **Do not** put the syringe back in the refrigerator once it has reached room temperature.
- **Do not** try to warm the syringe by using a heat source such as hot water or microwave.
- **Do not** leave the syringe in direct sunlight.
- **Do not** shake the syringe.

Important:

Always hold the pre-filled syringe by the syringe barrel.

B. Inspect the AMGEVITA pre-filled syringe.



Always hold the syringe by the syringe barrel.

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

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

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

C. Gather all materials needed for your injection(s).

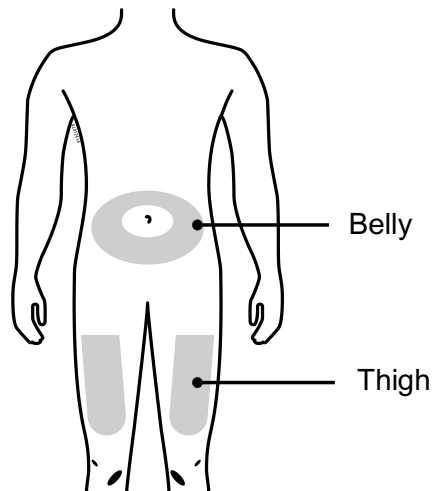
Wash your hands thoroughly with soap and water.

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

- New syringe(s)
- Alcohol wipes
- Cotton ball or gauze pad
- Adhesive bandage
- Sharps disposal container



D. Prepare and clean your injection site(s).



You can use:

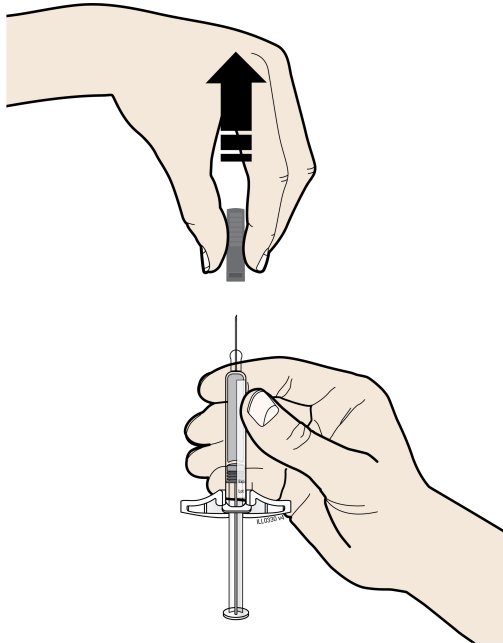
- Your thigh
- Stomach area (abdomen), except for a 5 centimetre (2 inch) area around your navel (belly button).

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

- **Do not** fan or blow on the clean area.
- **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.
- **Do not** inject through your clothes.

Step 2: Get ready

- E. Hold the pre-filled syringe by the syringe barrel with the needle cap pointing up. Carefully pull the needle cap straight out and away from your body when you are ready to inject.

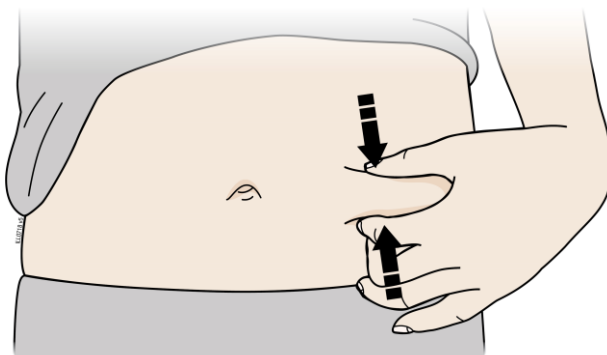


It is normal to see a drop of liquid at the end of the needle.

- **Do not** twist or bend the needle cap.
- **Do not** put the needle cap back onto the syringe.
- **Do not** remove the needle cap from the syringe until you are ready to inject.

Important: Throw the grey needle cap into the sharps disposal container.

- F. Pinch your injection site to create a firm surface.

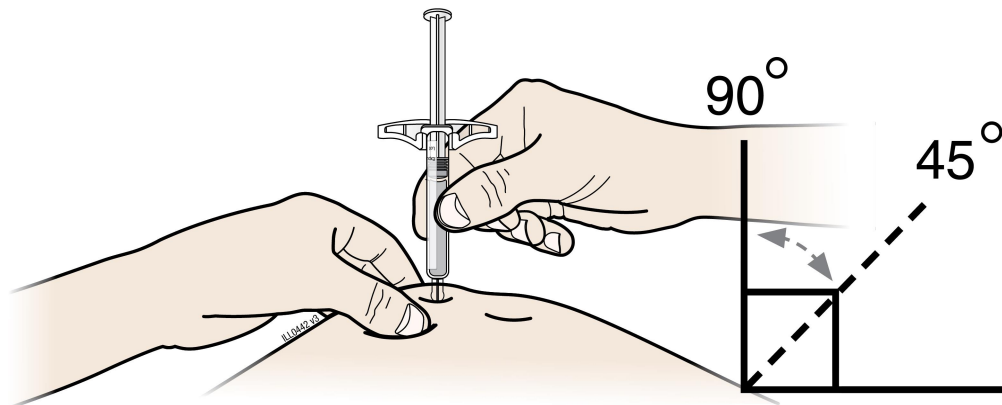


Pinch the skin firmly between your thumb and fingers, creating an area about 5 centimetres (2 inches) wide.

Important: Keep the skin pinched while injecting.

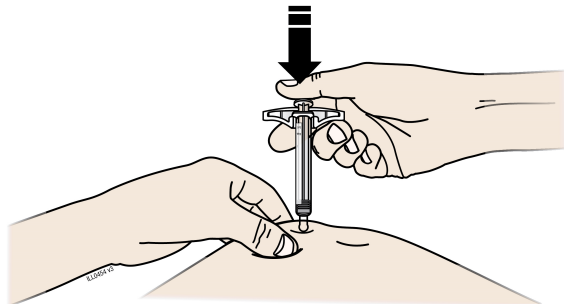
Step 3: Inject

- G. Hold the pinch. With the needle cap off, insert the syringe into your skin at 45 to 90 degrees.

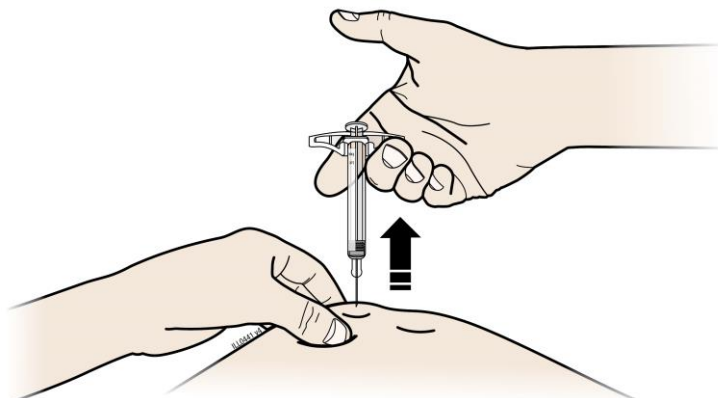


Do not place your finger on the plunger rod while inserting the needle.

- H. Using slow and constant pressure, push the plunger rod all the way down until it stops moving. **Do not** pull back the plunger rod while the needle is inserted.



- I. When completed, release your thumb, and gently lift the syringe off of your skin.



Step 4: Finish

- J. Discard the used syringe and the needle cap. **Do not** use any medicine that is left in the used syringe.



- Put the used AMGEVITA syringe in a sharps disposal container immediately after use. **Do not** throw away (dispose of) the syringe 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 with a tight-fitting, puncture-resistant lid, without sharps 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 or syringes. For more information, talk with your healthcare provider about proper disposal.
- **Do not** reuse the used syringe.
- **Do not** recycle the syringe 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.

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 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).

For more information, please contact AMGEN Medical Information on 1800 803 638 for help.

AMGEVITA® is a registered trademark of Amgen.

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SYMBOL TABLE			
 Prefilled Syringe	 Single Use	 CAUTION, Consult Accompanying Documents	 Lot Number

Date of last amendment: 11 November 2021

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