

AMGEVITA[®] Solution for Injection in Pre-filled Autoinjector

Adalimumab 50 mg/mL

What is in this leaflet?

1. What AMGEVITA is used for
2. How AMGEVITA works
3. Before you use AMGEVITA
4. How to use AMGEVITA
5. While you are using it
6. Side effects
7. Storage and Disposal of AMGEVITA
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of revision

What AMGEVITA is used for

AMGEVITA contains the active substance adalimumab, a selective immune-suppressive agent.

AMGEVITA is intended for treatment of rheumatoid arthritis, polyarticular juvenile idiopathic arthritis aged above 2 years old, axial spondyloarthritis (ankylosing spondylitis and Non-radiographic axial spondyloarthritis), psoriatic arthritis, enthesitis-related arthritis in children aged 6 years and above, psoriasis in adults and children aged 4 years and above, Crohn's disease in adults and children aged 6 years and above, ulcerative colitis in adults and children aged 6 years and above, hidradenitis suppurativa in adults and adolescents, and uveitis in adults and children aged 2 years and above.

How AMGEVITA works

It is a medicine that decreases the inflammation process of these diseases. The active ingredient, adalimumab, is a human monoclonal antibody produced by cultured cells. Monoclonal antibodies are proteins that recognise and bind to other unique proteins. Adalimumab binds to a specific protein (tumour necrosis factor or TNF α), which is present at increased levels in inflammatory diseases such as

rheumatoid arthritis, polyarticular juvenile idiopathic arthritis, axial spondyloarthritis (ankylosing spondylitis and Non-radiographic axial spondyloarthritis), psoriatic arthritis, psoriasis, ulcerative colitis, hidradenitis suppurativa, Crohn's disease, Uveitis and Enthesitis-Related Arthritis.

Before you use AMGEVITA

- When you must not use it

- If you are allergic (hypersensitive) to AMGEVITA or any of the other ingredients of AMGEVITA.
- If you have a severe infection, including active tuberculosis (see "Take special care with AMGEVITA"). It is important that you tell your doctor if you have symptoms of infections, e.g. fever, wounds, feeling tired, dental problems.
- If you have moderate or severe heart failure. It is important to tell your doctor if you have had or have a serious heart condition (see "Take special care with AMGEVITA").

Pregnancy and lactation

You should talk to your doctor if you become pregnant or are planning to have a baby.

According to a pregnancy study, there was no higher risk of birth defects when the mother had received adalimumab during pregnancy compared with mothers with the same disease who did not receive adalimumab.

You should talk to your doctor if you are breastfeeding or plan to breastfeed.

If you received adalimumab during pregnancy, your baby may have a higher risk of getting an infection.

It is important that you tell your baby's doctors and other health care professionals about your adalimumab use during your pregnancy before the baby receives any vaccine.

- Before you start to use it

- If you have an infection, including long-term or localized infection (for example, leg ulcer) consult your doctor before starting adalimumab.
- As cases of tuberculosis have been reported in patients treated with adalimumab, your doctors will check you for sign and symptoms of tuberculosis before starting adalimumab.
- Advise your doctor if you reside or travel in regions where fungal infections such as histoplasmosis coccidioidomycosis or blastomycosis are epidemic.
- Advise your doctor if you are a carrier of the hepatitis B virus (HBV), if you have active HBV or if you think you might be at risk of contracting HBV. Your doctor should test you for HBV. Adalimumab can cause reactivation of HBV in people who carry this virus. In some rare cases, especially if you are taking other medicines that suppress the immune system, reactivation of HBV can be life-threatening.
- Advise your doctor if you have a history of recurrent infections or other conditions that increase the risk of infections.

- Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop. Live vaccines may cause infections and should not be given while receiving adalimumab.

You should not take adalimumab with medicines containing the active substance, anakinra or abatacept. If you have questions, please ask your doctor.

How to use AMGEVITA

See the detailed “Instructions for Use” that comes with this patient information leaflet about the right way to prepare and administer AMGEVITA.

AMGEVITA is administered by injection under the skin (subcutaneous injection).

- How much to use

Follow all directions given to you by your doctor and pharmacist carefully. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

- When to use it

Use as directed by your doctor or pharmacist.

- How long to use it

Continue taking AMGEVITA for as long as your doctor recommends.

- If you forget to use it

Consult your doctor or pharmacist on what you should do if you forget to use it.

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

- If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are using it

- Things you must do

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are

taking AMGEVITA

Tell your doctor immediately if you become pregnant while taking this medication.

- Things you must not do

Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor.

Do not give AMGEVITA to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

Driving and using machines

AMGEVITA may have a minor influence on your ability to drive and use machines. Room spinning sensation and vision disturbances may occur after taking AMGEVITA.

Side effects

Like all medicines, AMGEVITA can cause side effects, although not everybody gets them.

Visit your doctor or pharmacist immediately if you experience any side effects after taking this medicine:

- Severe rash, hives or other signs of allergic reaction;
- Swollen face, hands, feet;
- Trouble breathing, swallowing;
- Shortness of breath with exertion or upon lying down or swelling of the feet;
- Signs and symptoms suggestive of blood disorders such as persistent fever, bruising, bleeding, paleness;

Tell your doctor as soon as possible if you notice any of the following:

- Signs of infection such as fever, feeling sick, wounds, dental problems, burning on urination;
- Feeling weak or tired;
- Coughing;
- Tingling;
- Numbness;
- Double vision;

- Arm or leg weakness;
- A bump or open sore that doesn't heal.
- Signs of liver problems such as yellowing of skin and/or eyes, severe tiredness, nausea and/or vomiting, bleeding or bruising, dark urine, or stomach pain.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of AMGEVITA

- Storage

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the label and carton after EXP. The expiry date refers to the last day of that month.

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

Store in the original carton in order to protect from light.

A single AMGEVITA pre-filled autoinjector may be stored at temperatures up to a maximum of 25°C for a period of up to 14 days. The pre-filled autoinjector must be protected from light, and discarded if not used within the 14-day period.

- Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help protect the environment.

Product Description

Contents of the pack and other information

- What it looks like

AMGEVITA is a clear and colourless to slightly yellow solution.

Each pack contains 2 single-use SureClick pre-filled autoinjectors.

Ingredients

- Active ingredient: adalimumab. Each pre-filled autoinjector contains 40 mg of adalimumab in 0.8 mL of solution.
- Inactive ingredients: glacial acetic acid, sucrose, polysorbate 80, sodium hydroxide and water for injection.

MAL numbers:

AMGEVITA Solution for Injection in Pre-filled Autoinjector 40 mg/0.8 ml
MAL19056105AZ

Manufacturer and Product Registration Holder

Manufacturer

Amgen Manufacturing Limited LLC
Road 31, Km. 24.6, Juncos,
Puerto Rico 00777, USA

Product Registration Holder

Amgen Biopharmaceuticals Malaysia Sdn Bhd,
Common Ground, 1 Powerhouse,
Horizon Penthouse, No. 1,
Persiaran Bandar Utama, Bandar
Utama, 47800 Petaling Jaya, Selangor,
Malaysia.

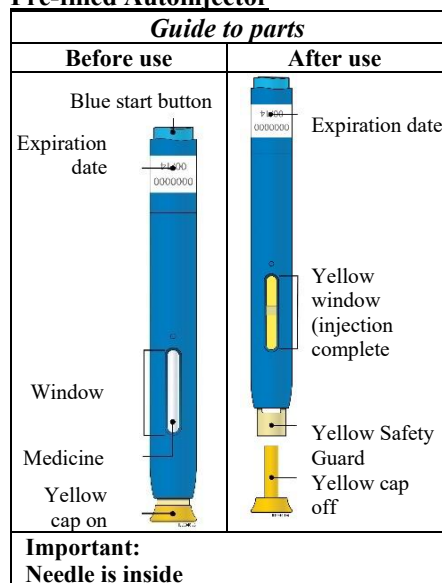
Date of revision

12/05/2026

Serial number

NPRA (R3/01) 03122024/0332

Instructions for Use: **AMGEVITA Single-Use SureClick®** **Pre-filled Autoinjector**



Important

Before you use the Single-Use AMGEVITA Pre-filled Autoinjector, read this important information:

- It is important that you do not try to give yourself or someone else the injection unless you or your caregiver has received training.
- **Do not** use an AMGEVITA pre-filled autoinjector if it has been dropped on a hard surface. Part of the AMGEVITA pre-filled autoinjector may be broken even if you cannot see the break. Use a new AMGEVITA pre-filled autoinjector.

Step 1: Prepare

A. Remove one AMGEVITA pre-filled autoinjector from the package.

Carefully lift the autoinjector straight up out of the box.

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

For a more comfortable injection, leave the pre-filled pen autoinjector at room temperature for **15 to 30** minutes before injecting.

- **Do not** put the pre-filled autoinjector back in the refrigerator once it has reached room temperature.

- **Do not** try to warm the pre-filled autoinjector by using a heat source such as hot water or microwave.
- **Do not** shake the autoinjector.
- **Do not** remove the yellow cap from the autoinjector yet.

B. Inspect the AMGEVITA pre-filled autoinjector.



Yellow cap on Window Medicine

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

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

In all cases, use a new autoinjector.

C. Gather all materials needed for your injection.

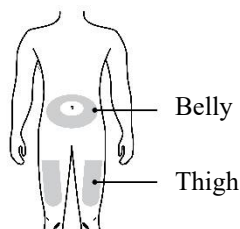
Wash your hands thoroughly with soap and water.

On a clean, well-lit work surface, place a new pre-filled autoinjector.

You will also need these additional items, as they are not included in the carton:

- Alcohol wipes
- Cotton ball or gauze pad
- Plaster
- Sharps disposal container



D. Prepare and clean your injection site.**You can use:**

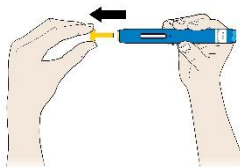
- Your thigh
- Belly, except for a 2-inch (5cm) area right around your belly button

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

- **Do not** touch this area again before injecting.
- 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.
- **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 off only when you are ready to inject.

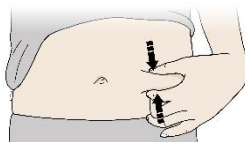


It is normal to see a drop of liquid at the end of the needle or yellow safety guard.

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

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 2 inches (5cm) wide.

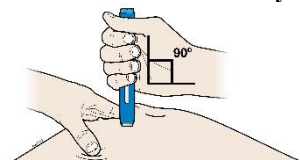
OR**Pinch method**

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

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

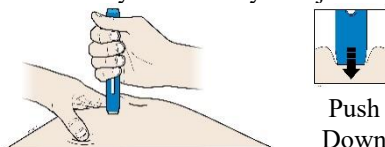
Step 3: Inject

- G.** Hold the stretched or pinched skin. With the yellow cap off, **PLACE** the pre-filled autoinjector on your skin at 90 degrees. **Important: Do not touch the blue start button yet.**



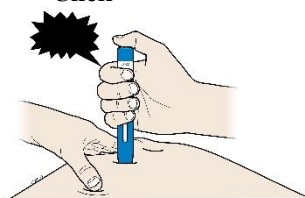
- H.** Firmly **PUSH** the pre-filled autoinjector down onto the skin until it stops moving.

Important: You must push all the way down but do not touch the blue start button until you are ready to inject.

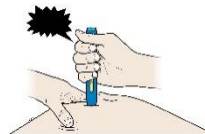


Push
Down

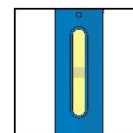
- I.** When you are ready to inject, **PRESS** the blue start button. "Click"



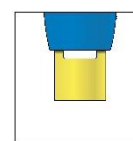
- J.** Keep **PUSHING** down on your skin. Your injection could take about 10 seconds.

"Click"

~10s



The window turns yellow when the injection is done

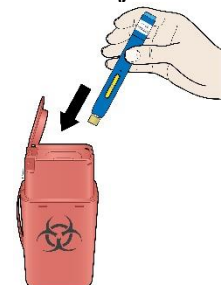


Note: After you remove the pre-filled autoinjector from your skin, the needle will be automatically covered.

Important: When you remove the pre-filled autoinjector, 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 autoinjector and yellow cap.



- Put the used pre-filled autoinjector in a sharps disposal container immediately after use. **Do not** throw away (dispose of) the pre-filled autoinjector in your household waste.
- Talk with your doctor or pharmacist about proper disposal. There may be local guidelines for disposal.
- **Do not** reuse the pre-filled autoinjector.
- **Do not** recycle the pre-filled autoinjector 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 a plaster if needed.

MYAMGAIPIL06



AMGEVITA® and SureClick® are registered trademarks owned or licensed by Amgen Inc., its subsidiaries, or affiliates.