

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

Adalimumab 100 mg/ml

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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 0.4 ml of solution.
- Inactive ingredients: sucrose, polysorbate 80, L-lactic acid, sodium hydroxide and water for injection.

- MAL numbers:

AMGEVITA Solution for Injection in
Pre-filled Autoinjector 40 mg/0.4 ml
MAL25076012AZ

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

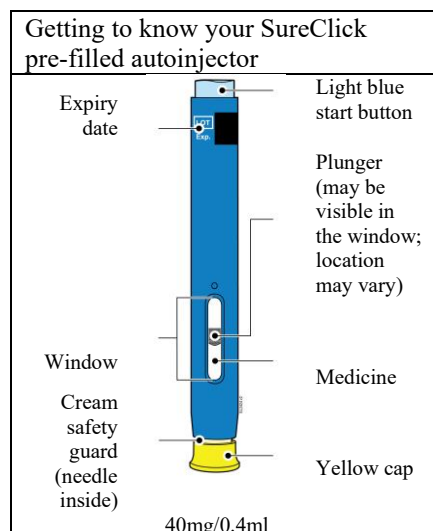
12/05/2026

Serial number

NPRA (R3/01) 09012026/0346

Instructions for Use:

AMGEVITA Single-Use SureClick® Pre-filled Autoinjector



1. Important information you need to know before injecting AMGEVITA

- It is important that you do not try to give yourself the injection until you have fully read and understood this Instructions for Use and unless you have received training from your doctor or healthcare provider.
- Do not** use the pre-filled autoinjector if the carton is damaged or seal is broken.

- Do not** use the pre-filled autoinjector after the expiry date on the label.
- Do not** shake the pre-filled autoinjector.
- Do not** remove the yellow cap from the pre-filled autoinjector until you are ready to inject.
- Do not** use the pre-filled autoinjector if it has been frozen.
- Do not** use the pre-filled autoinjector if it has been dropped on a hard surface. Part of the pre-filled autoinjector may be broken even if you cannot see the break. Use a new pre-filled autoinjector and call your doctor or healthcare provider.

Important: Keep the pre-filled autoinjector and sharps disposal container out of the sight and reach of children.

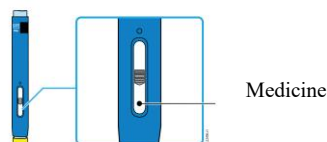
2. Preparing to inject AMGEVITA

2a. Wait 15 to 30 minutes for the pre-filled autoinjector to reach room temperature.

**WAIT
15 to 30
minutes**

- Remove the number of pre-filled autoinjectors you need for your injection and put any unused pre-filled autoinjectors back into the refrigerator.
- Let the pre-filled autoinjector warm up naturally.
- Do not** heat the pre-filled autoinjector with hot water, a microwave, or direct sunlight.
- Do not** shake the pre-filled autoinjector at any time.
- Do not** place the pre-filled autoinjector back in refrigerator after it has reached room temperature.
- Using the pre-filled autoinjector at room temperature makes sure the full dose is delivered and allows for a more comfortable injection.

2b. Inspect the medicine. It should be clear and colourless to slightly yellow.

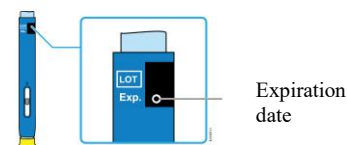


- It is okay to see air bubbles in the pre-filled autoinjector.

- Do not** use if the medicine is cloudy, discoloured or has flakes or particles.

Important: If the medicine is cloudy, discoloured, or contains flakes or particles, or if the pre-filled autoinjector is damaged or expired, call your doctor or healthcare provider.

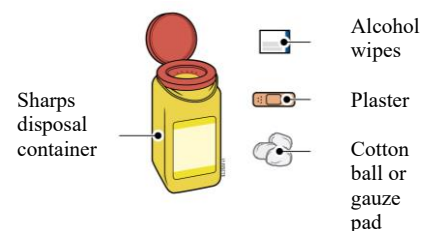
2c. Check the expiry date (EXP.) and inspect the pre-filled autoinjector for damage.



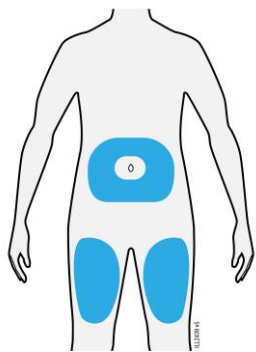
- Do not** use the pre-filled autoinjector if the expiry date has passed.
- Do not** use the pre-filled autoinjector if:
 - the yellow cap is missing or loose.
 - it has cracks or broken parts.
 - it has been dropped on a hard surface.
- Make sure you have the right medicine and dose.

3. Getting ready for your injection

3a. Gather and place the following items for your injection on a clean, flat and well-lit surface.



- AMGEVITA pre-filled autoinjector (room temperature)
- Sharps disposal container
- Alcohol wipe
- Plaster
- Cotton ball or gauze pad

3b. Inject into 1 of these sites.

- Inject into the front of your thigh or belly (except 5 centimetres around your belly button).
- Choose a different site for each injection.
- Wash your hands thoroughly with soap and water.
- Clean the injection site with an alcohol wipe.
- Let the skin dry on its own.
- **Do not** touch this area again before injecting.

Important: Avoid areas with scars, stretch marks, or where the skin is tender, bruised, red or hard.

4. Injecting AMGEVITA

Important: Only remove the yellow cap when you can inject right away (within 5 minutes) because the medicine can dry out. Do not recap.

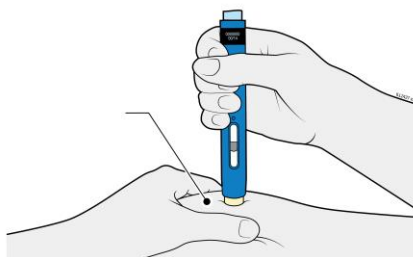
- 4a. Hold the pre-filled autoinjector so you can see the window. Pull the yellow cap straight off. You may need to pull hard.**

Window should be visible

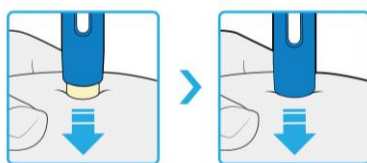


- **Do not** twist, bend or wiggle the yellow cap to pull it off.
- **Never** put the needle cap back on. It may damage the needle.
- **Do not** put your finger inside the cream safety guard.
- It is normal to see a drop of medicine at the end of the needle or cream safety guard.

- 4b. Pinch the skin to create a firm surface at the injection site. Place the cream safety guard straight against the pinched skin.**

PINCH skin at injection site

- Keep the skin **pinched** until the injection is finished.
- Make sure you can see the window.
- Make sure the pre-filled autoinjector is positioned straight on the injection site (at a 90 degree angle).

PUSH and hold against skin

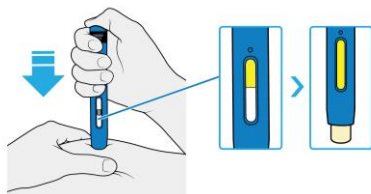
- 4c. Firmly push the pre-filled autoinjector down until the cream safety guard stops moving. Hold the pre-filled autoinjector down; do not lift.**

- The cream safety guard pushes in and unlocks the light blue start button.

PRESS light blue start button

- 4d. Keep pushing the pre-filled autoinjector down and press the light blue start button to start the injection.**

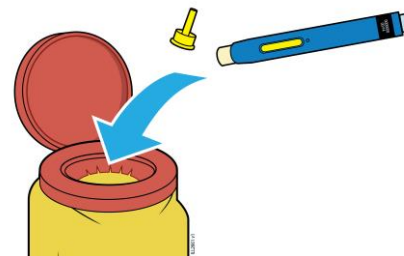
- You may hear or feel a click.
- The window starts to turn yellow.
- It is okay to let go of the light blue start button.

WATCH and CONFIRM that the window turns fully yellow

- 4e. Keep pushing the pre-filled autoinjector down. When the window is fully yellow, the injection is complete.**

- The injection may take up to **10** seconds to complete.
- You may hear or feel a click.
- Lift the pre-filled autoinjector away from your skin.
- The cream safety guard locks around the needle.

Important: If the window has not turned fully yellow, or it looks like the medicine is still coming out, you have not received a full dose. Call your doctor or healthcare provider right away.

5. Disposing of AMGEVITA and checking the injection site

Important: Do not throw away the pre-filled autoinjector into your household waste.

- 5a. Place the used pre-filled autoinjector and yellow cap in a sharps disposal container right away after use.**

- **Do not** re-use the pre-filled autoinjector
- **Do not** touch the cream safety guard

5b. Check the injection site.

- **Do not** rub the injection site.
- If there is blood, press a cotton ball or gauze pad on your injection site. Apply a plaster if necessary.

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