



AMGEVITA[®] (adalimumab)
A GUIDE TO UNDERSTANDING
AND USING AMGEVITA[®]

AmgenCare is a patient service provided by Amgen

**This booklet is only intended for patients
in Great Britain who have been prescribed AMGEVITA[®]**

If you get side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in the package leaflet. You can also report side effects directly via the Yellow Card Scheme at <https://yellowcard.mhra.gov.uk/> or search for MHRA Yellow Card app in the Google Play or Apple store. By reporting side effects you can help provide more information on the safety of this medicine. Side effects should also be reported to Amgen Ltd on +44 (0) 1223 436441

AMGEN[®]
care

www.amgencare.co.uk

WELCOME TO AMGEVITA®

Living with an autoimmune disease is not always easy, but medication can provide some relief for your symptoms. This simple guide is provided to help you to understand how to manage your treatment with AMGEVITA®.

- Please read both this patient booklet and the information leaflet that comes with your medication pack
- You'll find a **Patient Reminder Card** at the back of this booklet. Complete it, including entering information on any tuberculosis tests and place it in your wallet. It contains important safety information and highlights important contact and medical information; and in the event of an emergency, it will tell a healthcare professional that you are taking a specific medication
- A video demonstration on how to use the SureClick® pen and pre-filled syringe is available at www.amgencare.co.uk. This can also be accessed using the QR code at the back of this booklet
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours

AMGEVITA® is a registered trademark of Amgen Inc.



Remember, you should always ask your doctor or nurse any specific questions about your condition.

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ABOUT AMGEVITA®

WHAT IS AMGEVITA®?

AMGEVITA® is a biosimilar that contains the active substance adalimumab, a medicine that acts on your body's immune (defence) system.

Adalimumab binds to a specific protein (tumour necrosis factor or TNF α), which is present at increased levels in certain inflammatory diseases.

AMGEVITA® is a biosimilar medicine, meaning it is another version of the original biological medicine, in this case Humira®. It works in the same way. AMGEVITA® has been rigorously tested to ensure that there is no difference in how AMGEVITA® treats a condition compared to the original medicine.

HOW DOES AMGEVITA® WORK?

AMGEVITA® is injected under the skin (subcutaneous use) with a specially designed pen called SureClick® or using a pre-filled syringe. The medication is then absorbed into the bloodstream to work on the underlying cause of your symptoms.

AMGEVITA® helps to block the action of the protein TNF α (Tumour Necrosis Factor) which occurs naturally in the immune system. When the body produces too much TNF α as a result of certain inflammatory diseases, problems with the body's immune system can arise.

WHAT BENEFITS CAN I EXPECT FROM AMGEVITA® AND WHEN?

Treatments work differently for everyone; however, you should start to feel some noticeable relief from your symptoms within 12–16 weeks.

If you believe that AMGEVITA® is not working for you, please tell your doctor or nurse.

INJECTING AMGEVITA®

Your doctor or nurse will train you on how to inject yourself with AMGEVITA® using either the SureClick® pen or pre-filled syringe.



Amgevita SureClick® device



Amgevita 20mg Pre-filled syringe



Amgevita 40mg Pre-filled syringe

Each injection of AMGEVITA® contains either 20mg or 40mg of adalimumab and should be administered as often as directed by your doctor or nurse prescriber. Always follow your doctor or nurse's instructions on when to use your medication. Ensure that you record the batch number on the side of the box that contains the SureClick® pen or pre-filled syringe. This will allow for easier traceability should you have any side effects.

Using the tracker at the back of this booklet, marking up a calendar or setting alerts on your phone makes it easier to keep tabs on your treatment schedule.

WHERE TO INJECT?

AMGEVITA® should be injected in your belly (except for a 2 inches/5 centimetres area around your belly button) or your thigh - see diagram on page 21.

Each time you inject, make sure it is not the same spot on the injection site you used for a previous injection.

Allergies

It is important that you tell your health care professional if you have any allergies. Amgen are no longer manufacturing the AMGEVITA® Sureclick® prefilled pen with latex, however there will still be a latex AMGEVITA® Sureclick® prefilled pen available until it is eventually removed from the pharmacy/dispensary supply chain.

IMPORTANT. If you have a latex allergy please inform your prescriber, dispensing pharmacist and nurse so they can ensure you are given the latex free pen or syringe.



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-BY-STEP GUIDES ON HOW TO INJECT AMGEVITA®

SURECLICK® PEN

STEP 1: CHECKING THE PEN

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

Take the pen out of the fridge without shaking it.

Do not use the SureClick® pen if the following applies and use a new pen:

- ✗ It has passed the expiry date
- ✗ The solution appears cloudy, discoloured or contains flakes or particles in the window of the pen shaft
- ✗ It is frozen
- ✗ The pen has been dropped on a hard surface, appears damaged or the yellow cap is missing or not securely attached.



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

STEP 2: GETTING READY

First wash your hands thoroughly with soap and water.

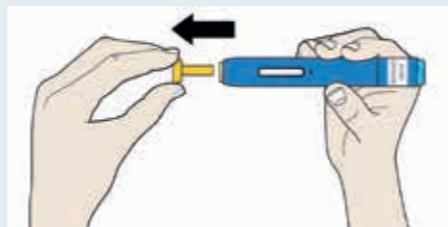
Then, on a clean surface, lay out the following:

- ✓ A new SureClick® pen
- ✓ Sharps disposal container
- ✓ Alcohol wipes
- ✓ Plaster (if needed)
- ✓ Cotton wool or gauze pad

You will need to clean your injection site with an alcohol wipe and 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.

STEP 3: INJECTING



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 SureClick® pen.
- ✗ **Do not** remove the yellow cap from the SureClick® pen until you are ready to inject.
- ✗ **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.

HOW TO INJECT

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



The stretch method

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



The pinch method

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



Keep the skin stretched or pinched while injecting.



Hold the stretch or pinch. With the yellow cap off, it is **important** to place the SureClick® pen on your skin at 90 degrees.



Do not touch the blue start button yet.



Firmly push the SureClick® pen down onto the skin until it stops moving. It is important to ensure the yellow safety guard is fully depressed before pressing the blue button.



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



When you are ready to inject, press the blue start button once. You will hear a click.

Keep pushing down on the skin. Your injection could take about 10 seconds.



The window turns yellow when the injection is done. You may hear a second click.

Note: After you remove the SureClick® pen from your skin, the needle will be automatically covered.



When you remove the SureClick® 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 doctor immediately.

PRE-FILLED SYRINGE

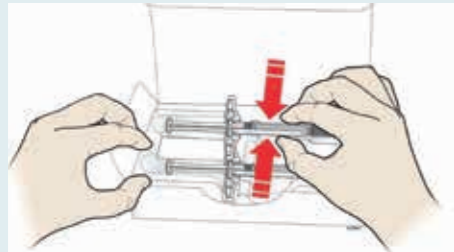
STEP 1: CHECKING THE SYRINGE

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

Remove the number of AMGEVITA® pre-filled syringes you need from the package without shaking it.

Do not use the pre-filled syringe if the following applies and use a new syringe(s):

- ✗ It has passed the expiry date
- ✗ It is frozen
- ✗ The solution appears cloudy, discoloured or contains flakes or particles
- ✗ The syringe has been dropped, appears damaged or the needle cap is missing or not securely attached.



Grab the syringe barrel to remove the syringe from the tray.

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

For safety reasons:

- ✓ Always hold the pre-filled syringe by the syringe barrel
- ✗ Do not grasp 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

- ✗ Do not put the syringe back in the fridge once it has reached room temperature
- ✗ Do not heat the syringe for example using a microwave or hot water
- ✗ Do not leave the syringe in direct sunlight

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

STEP 2: GETTING READY

First wash your hands thoroughly with soap and water.

Then, on a clean surface, lay out the following:

- ✓ The pre-filled syringe
- ✓ Sharps disposal container
- ✓ Alcohol wipes
- ✓ Plaster (if needed)
- ✓ Cotton wool or gauze pad

STEP 3: INJECTING

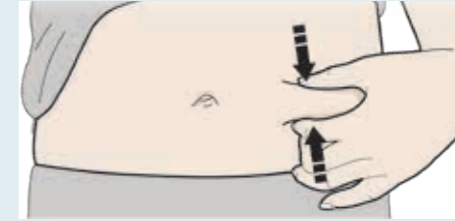


Pull the needle cap straight out and away from your body when you are ready to inject.

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

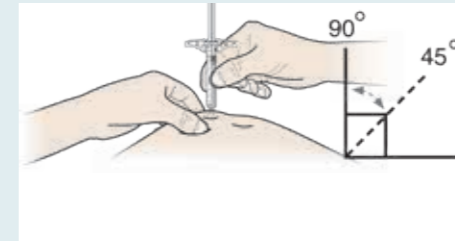
- ✗ Do not twist or bend the needle cap.
- ✗ Do not put the needle cap back onto the syringe.
- ✗ Do not remove the needle cap from the syringe until you are ready to inject.

HOW TO INJECT



Pinch your injection site to create a firm surface. Pinch the skin firmly between your thumb and fingers, creating an area about 2 inches/5 centimetres wide.

Keep the skin pinched while injecting.

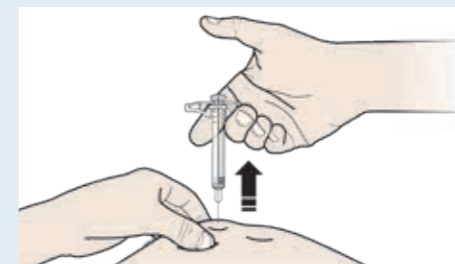


Hold the pinch. With the needle cap off, insert the pre-filled syringe into your skin at 45 to 90 degrees.

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



Using slow and constant pressure, push the plunger rod all the way down until it stops moving.



When complete, release your thumb, and gently lift the syringe off your skin.

DISPOSING OF EITHER YOUR SURECLICK® PEN OR PRE-FILLED SYRINGE



Discard the used pen and yellow cap, or pre-filled syringe and cap, in a sharps disposal container immediately after use.

Talk with your doctor or pharmacist about proper disposal. There may be local guidelines for disposal.

- ❌ Do not reuse the used pen or syringe.
- ❌ Do not use any medicine that is left in the used pen or syringe.
- ❌ Put the used AMGEVITA® pen or syringe in a sharps disposal container immediately after use. Do not throw away (dispose of) in your household waste.
- ❌ Do not recycle the pen or syringe or sharps disposal container or throw them into the household waste.



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

STORING THE AMGEVITA® SURECLICK® PEN OR PRE-FILLED SYRINGE

Please ensure that you store your SureClick® pen or pre-filled syringe:

- ✓ Out of the sight and reach of children
- ✓ In the original carton in order to protect it from light
- ✓ In the refrigerator (2°C to 8°C). Refrigerated product can be kept for the duration of the shelf life. Do not freeze
- ✓ At temperatures up to a maximum of 25°C for a period of up to 14 days. The pre-filled syringe or SureClick® pen must be protected from light, and discarded if not used within the 14-day period.

AFTER INJECTING AMGEVITA®

Examining 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.

If you have any concerns about the injection site, for example: pain, redness, itching or swelling — please inform your doctor or nurse.

Side effects to look out for and what to do if you feel unwell

Like all medicines, AMGEVITA® can cause side effects, although not everybody gets them. Most side effects are mild to moderate. However, some may be serious and require treatment.

Side effects that could happen with AMGEVITA® include allergic reactions, infections, cancer and problems with your nervous system.

Some side effects observed with AMGEVITA® may not have symptoms and may only be discovered through blood tests.

You'll be screened for tuberculosis (TB) and other infectious diseases before starting treatment.

If you get side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in the package leaflet. You can also report side effects directly via the Yellow Card Scheme at <https://yellowcard.mhra.gov.uk/> or search for MHRA Yellow Card app in the Google Play or Apple store. By reporting side effects you can help provide more information on the safety of this medicine. Side effects should also be reported to Amgen Ltd on +44 (0) 1223 436441

Tell your doctor **immediately** if you notice any of the following signs of allergic reaction or heart failure:

- Severe rash, hives, other signs of allergic reaction
- Swollen face, hands, feet
- Trouble breathing, swallowing
- Shortness of breath with exertion or lying down or swelling of the feet

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
- Signs of skin cancer such as a bump or open sore that doesn't heal
- Signs and symptoms suggestive of blood disorders such as persistent fever, bruising, bleeding, paleness

Side effects may occur at least up to 4 months after the last AMGEVITA® injection.

Please read the full list of side effects of AMGEVITA® in the Patient Information Leaflet which is in the product carton or can be requested from your healthcare team.



It can also be found by searching for AMGEVITA® at: <https://www.medicines.org.uk/emc>

Consult your healthcare team if you are experiencing any new symptoms on AMGEVITA®.

FREQUENTLY ASKED PATIENT QUESTIONS

Why do I need to stay on treatment if I'm feeling better?

Even if you are feeling better after using AMGEVITA[®], because your condition is long term and chronic, you need to continue with your medication as instructed by your doctor. For any questions about your treatment or condition, talk to your doctor.

What if I miss a dose?

If you forget to take a dose, inject as soon as you remember. From then on, continue injecting on your normal due day.

What if I accidentally take a dose too early?

Talk to your doctor or nurse if you inject more frequently than you have been asked to. Always take the outer carton of this medicine with you, even if it is empty.

What about travelling with my medication?

AMGEVITA[®] may be stored in its original carton (protected from light) at room temperature up to 25°C for a maximum of 14 days, so it is suitable for taking away on holiday for certain periods of time. Please remember to speak with your nurse, doctor or pharmacist before you go away.

What if I leave my medication out of the fridge?

AMGEVITA[®] should be kept in a refrigerator (2°C to 8°C). If left out it may be stored at room temperature up to a maximum of 25°C in its carton (protected from light) for a maximum period of 14 days. After this time AMGEVITA[®] should be discarded. AMGEVITA[®] should not be put back in the fridge if left out at room temperature.

Should I avoid vaccinations with AMGEVITA[®]?

Certain vaccines may cause infections and should not be given while receiving AMGEVITA[®].

Please check with your doctor before you receive any vaccines.



Can I take AMGEVITA® if I'm pregnant?

You should consider the use of adequate contraception to prevent pregnancy and continue its use for at least 5 months after the last AMGEVITA® treatment.

If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor for advice about taking this medicine.

AMGEVITA® should only be used during pregnancy if needed.

If you receive AMGEVITA® during your pregnancy, your baby may have a higher risk of getting an infection.

It is important that you tell your baby's doctors and other healthcare professionals about your AMGEVITA® use during your pregnancy before the baby receives any vaccines.

Speak to your healthcare team for further advice.



Can I take AMGEVITA® if I'm breastfeeding?

AMGEVITA® can be used during breast-feeding.



Can I drive or use machines after taking AMGEVITA®?

AMGEVITA® may have a minor influence on your ability to drive, cycle or use machines. Room spinning sensation (vertigo) and vision disturbances may occur after taking AMGEVITA®. Speak to your healthcare team for further advice.

AMGEN HOMECARE SUPPORT SERVICES

- We work with recognised homecare providers for convenient access to AMGEVITA® when you need it.
- You'll also get access to face-to-face injection training sessions with registered nurses and hints and tips on the AmgenCare website at www.amgencare.co.uk.
- You can access a SureClick® pen and pre-filled syringe training video by scanning the QR code found at the back of this booklet.

ADVICE IF YOU STILL HAVE ANY CONCERNS

If after reading this booklet, you still have any concerns please contact one of the healthcare specialists looking after you:

MY MAIN CONTACT IS:

Phone: _____

Email: _____

MY SECOND CONTACT IS:

Phone: _____

Email: _____

MY HOMECARE PROVIDER IS:

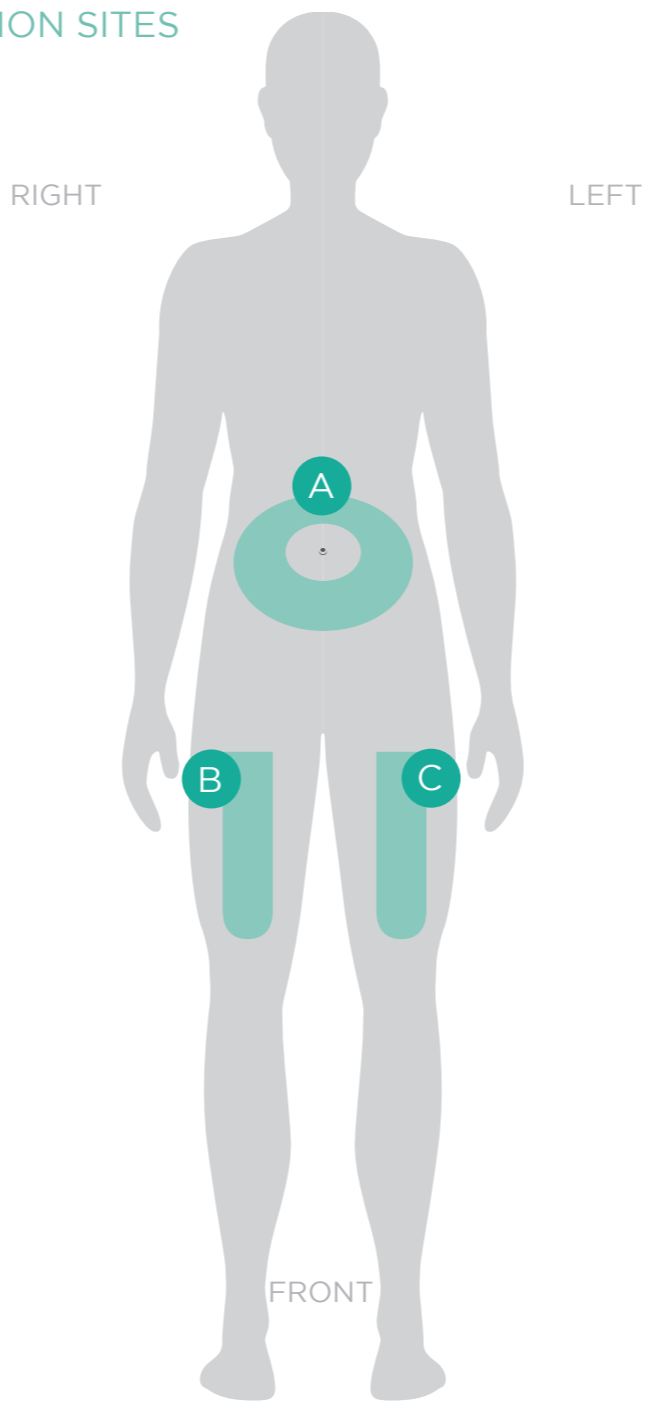
INJECTION TRACKING CHART TO SHARE WITH YOUR NURSE

This chart is to help you to track injection sites on your body

Make a note of the expiry and batch number in case you experience any issues

SITE(A/B/C)	DATE	TIME	BATCH/LOT NUMBER	EXPIRY DATE

INJECTION SITES

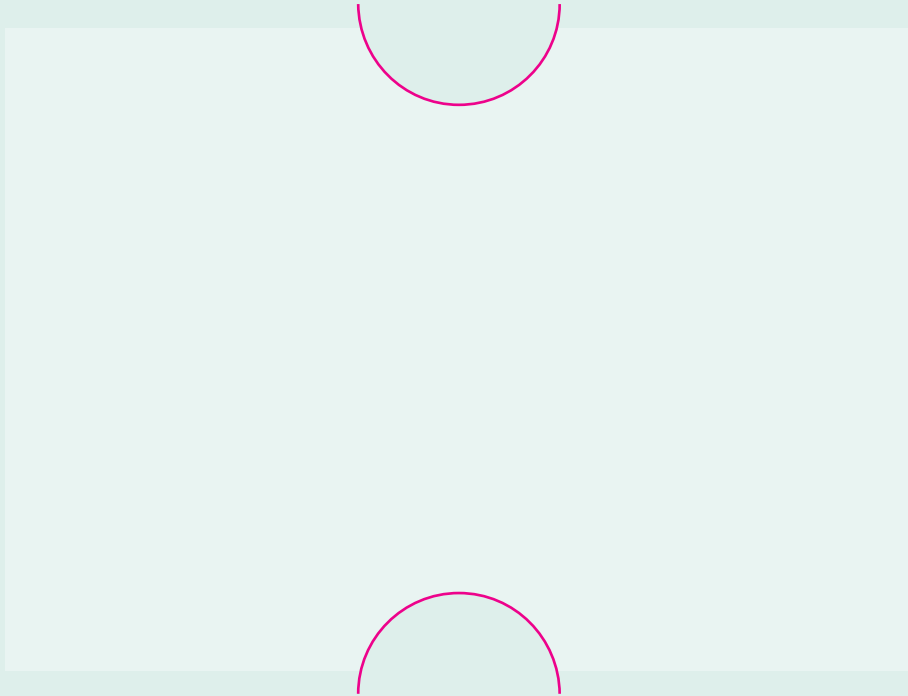


NOTES:

Lined area for notes with two pink curved lines drawn on the lines.

PATIENT REMINDER CARD

Put this Patient Reminder Card in your wallet, purse or bag so that you've always got it with you while you're taking AMGEVITA® and for 4 months after the last dose.



More information is available at www.amgencare.co.uk.

Use this QR to access:

1. Open the QR Code reader on your phone.
2. Hold your device over the QR Code so that it's clearly visible within your smartphone's screen.
3. The phone automatically scans the code or you may need to press a button to snap a picture.



FOR FURTHER INFORMATION PLEASE REFER TO THE PATIENT INFORMATION LEAFLET THAT CAME WITH YOUR MEDICINE.

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www.amgencare.co.uk

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