



UNDERSTANDING MY TREATMENT WITH AMGEVITA® (adalimumab)

AmgenCare is a patient service provided by Amgen

This booklet is only intended for patients in Northern Ireland 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

Your doctor or nurse will have shown you or your parent/carer how to use AMGEVITA®. Please read the leaflet that comes inside the medication pack.

You can also visit www.amgencare.co.uk for a video on how to use the pen or syringe you have been given. Please scan the QR code at the back of this booklet.

There is a reminder card for you at the back of this booklet with important information and contacts. Carry it with you at all times.



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The photos throughout this guide are posed by models.

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AMGEVITA® AND ME

WHAT IS AMGEVITA®

AMGEVITA® is a medicine which helps to calm down some inflammatory conditions (affecting joints, eyes, skin and digestive tract).

HOW DOES IT WORK?

Your body uses a protein from your immune system called Tumour Necrosis Factor (or TNF α) which fights infections. In some people too much TNF α is made, and inflammation goes on for longer than it should.

AMGEVITA® sticks to the TNF α and helps to calm inflammation. So it can help to lessen some of the symptoms of inflammation like joint pain, diarrhoea and skin changes.

WHY HAVE I BEEN PRESCRIBED IT?

AMGEVITA® can be used in children and young people with different inflammatory conditions.

These include:

- Polyarticular juvenile idiopathic arthritis (JIA)
- Enthesitis-related arthritis
- Crohn's disease
- Ulcerative colitis
- Plaque psoriasis
- Hidradenitis suppurativa (acne inversa)
- Uveitis

You can't
give these
conditions to
other people



Polyarticular juvenile idiopathic arthritis

Polyarticular juvenile idiopathic arthritis (usually shortened to JIA) is an inflammatory condition in people that are younger than 16 years old. The immune system has become hyperactive and wrongly sees your joints as 'alien'. This means your immune system will attack your joints and make them look red, feel sore and painful.

Enthesitis-related arthritis

This is inflammation that affects the places where the tendons attach to the bone and you may suffer from pain in the bottoms of your feet, around your hips, knees or in your back.

Crohn's disease

This is a chronic inflammatory disease of unknown origin, which can affect any part of the digestive tract from the mouth to the anus. Symptoms can vary but can include stomach pain, nausea (feeling sick), vomiting (being sick), and persistent diarrhoea (possibly with blood or mucus in your poo).

Ulcerative Colitis

This is an inflammatory disease of the large intestine. Symptoms can include: recurring diarrhoea, which may contain blood, mucus or pus; abdominal pain and needing to empty the bowels frequently.

Plaque psoriasis

Skin cells are made constantly by the body, but in plaque psoriasis this happens up to five times more quickly. Scales form on the skin from the excess skin cells, giving raised scaly patches known as plaques. Some of these plaques can be itchy but are not usually painful. Any part of the skin surface can be affected but the plaques are usually seen on the elbows, knees and scalp.

Hidradenitis suppurativa

A skin condition that causes abscesses and scarring under the skin where there are sweat glands, usually around the groin, buttocks, breasts and armpits.

Uveitis

Inflammation in the middle layer of the eye (called the uvea) causing eye pain and changes to vision.

AMGEVITA® can help to reduce the symptoms of these conditions and help you to feel better and carry on with your day. It may mean you need less of your other medications (Please check with your doctor before changing any of your other medications).

AMGEVITA® AND ME

HOW AND WHEN IS IT GIVEN?

AMGEVITA® is injected under the skin (a subcutaneous injection) with a specially designed pen called SureClick® or using a pre-filled syringe.



Amgevita SureClick® device

Amgevita 20mg Pre-filled syringe



Amgevita 40mg Pre-filled syringe

AMGEVITA® should be injected into your thigh or belly (except for a 2 inches/ 5 centimetres area around the button). See diagram on page 23.

The medicine travels into your bloodstream to work on the areas that are inflamed and causing your symptoms.

Your doctor, pharmacist or nurse will show you or your parent/carer how to give the injection. It's important the injection is given correctly for it to work.

You may have the injection in hospital or at home. You can give it to yourself or your parent/carer can do this for you. Usually, the injection is given every 2 weeks, but your doctor may change this to best suit what works for you.

You need to follow the advice of your healthcare team and ask to speak to them if you are not feeling well.

For full and detailed instructions on how to administer your AMGEVITA®, please read the instructions provided in the product carton.

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
- ✗ It is frozen
- ✗ The solution appears cloudy, discoloured or contains flakes or particles in the window of the pen shaft
- ✗ 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

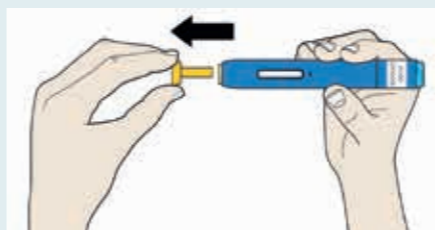
First wash your hands thoroughly with soap and water.

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

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

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.

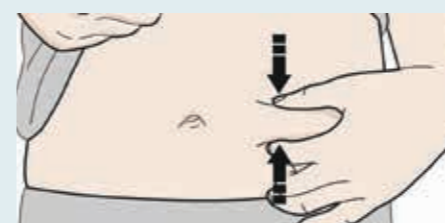
HOW TO INJECT

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



The stretch method

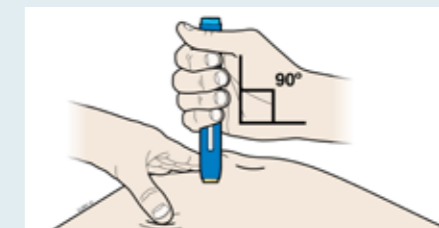
Stretch skin firmly by moving your thumb and fingers in the opposite direction, creating an area about 2 inches/ 5 centimetres wide.



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 that 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

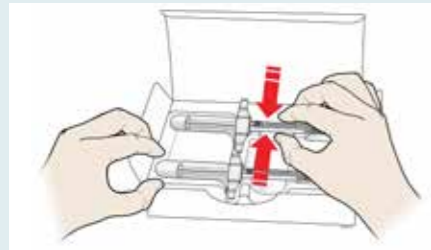
STEP 1: CHECKING THE SYRINGE

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.**

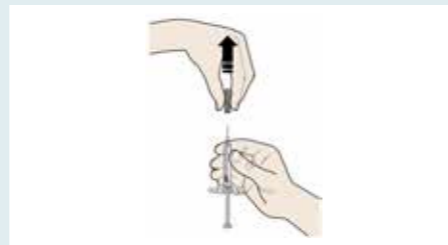
STEP 2: GETTING READY

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

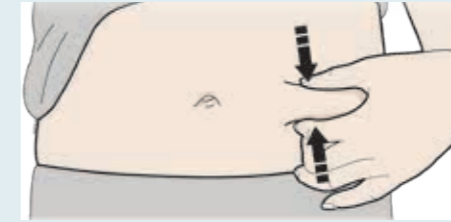


Pull the needle cap straight out and away from your body when you are ready to inject.

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.**

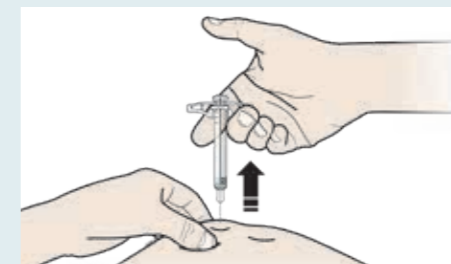


Hold the pinch. With the needle cap off, insert the pre-filled syringe into your skin at 45 to 90 degrees.

⚠ **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.

HOW LONG DOES IT TAKE TO WORK?

It can take 12-16 weeks to work fully. Your symptoms may get better sooner than this depending on the condition you are being treated for.

It's also possible that AMGEVITA® may not work for you. If you feel it's not working or not working as well as it did before, you should speak to your healthcare team.

TRAVEL/STORAGE ADVICE

AMGEVITA® may be stored in its original carton (protected from light) at room temperature up to a (maximum of 25°C) for up to 14 days. It can be taken away on holiday for certain periods of time.

It is important to:

- Only take what you need whilst you are away
- Make a note of the date you take AMGEVITA® from the fridge
- Keep it in your carry-on hand luggage
- Then keep it at room temperature protected from light, in the carton
- If more than 14 days have passed since you took it out of the fridge throw it away. It is fine to use the injection if it has been stored for less 14 days at room temperature

Please remember to speak with your nurse, doctor or pharmacist before you go away.

AMGEVITA[®] AND ME

DO I NEED ANY SPECIAL CHECKS BEFORE STARTING AMGEVITA[®]?

You may have blood tests before starting treatment. Sometimes these show up infections you didn't know you had. AMGEVITA[®] shouldn't be given until these infections have been treated.

For example some people can carry tuberculosis (TB), but not know that they have it. TB can be found using blood tests and chest X-rays. TB infections will need to be treated before you can start AMGEVITA[®].

POSSIBLE SIDE EFFECTS

Like all medicines, AMGEVITA[®] can cause side effects, although not everyone gets them. Most side effects are mild or moderate but some may be serious and require treatment.

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

You will need to notify your healthcare team **immediately** if you experience any of the following signs of allergic reaction or heart failure:

- Severe rash, hives (redness on the skin or red spots) or other signs of allergic reaction
- Swollen face, hands, feet
- Trouble breathing or swallowing
- Shortness of breath with exertion or lying down or swelling of the feet

Tell your doctor and parent(s)/carer as soon as possible if you notice any of the following:

- Signs of infection such as fever (feeling hot), feeling sick, wounds, teeth problems, burning when you pee
- 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



Please read the reminder card provided at the end of this booklet or by your Doctor or nurse

This is not a full list of side effects. Please read the leaflet in the carton for complete information on potential side effects

AMGEVITA[®] AND ME

REPORTING OF SIDE EFFECTS

Side effects that could happen with AMGEVITA[®] include allergic reactions, infections, cancer and problems with your nervous system. Speak to your doctor or nurse about the pros and cons of starting treatment with anti TNF therapies like AMGEVITA[®].

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

A full list of side effects are available in the AMGEVITA[®] Patient Information Leaflet available in the product carton, or given to you by your healthcare team.

It can also be found by searching for AMGEVITA[®] at: <https://www.emcmedicines.com/en-gb/northernireland/>

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

MONITORING OF TREATMENT

Blood tests will be taken while you're on treatment to check how you are and what effects the treatment is having on you.

Your healthcare team will discuss with your treatment plan with you and how often you may require blood tests or how well it is working

WHY DO I NEED TO STAY ON TREATMENT IF I'M FEELING BETTER?

Even if you are feeling better after using AMGEVITA[®], you will need to continue with your medication as instructed by your healthcare team because your condition is long term.

Missing doses or stopping your treatment without speaking to your healthcare team will not keep your condition well controlled.

For any questions about your treatment or condition, talk to your healthcare team.

REMINDER CARD

There is a special reminder card and you should keep this card with you at all times while you are taking AMGEVITA® and for 4 months after your last injection of AMGEVITA®.

This should be shown to all of your healthcare providers in case you experience any side effects whilst on treatment with AMGEVITA®.

It is important to know that the possible side effects listed on this card are not the only side effects of AMGEVITA®. For more comprehensive information, please read the AMGEVITA® patient information leaflet (PIL) available in the product carton, or given to you by your doctor or available by searching for AMGEVITA® at: <https://www.emcmedicines.com/en-gb/northernireland/>

DRIVING AND USING MACHINES

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®.

PREGNANCY AND BREAST FEEDING

If you are sexually active, 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 a pregnancy if needed

AMGEVITA can be used during breast-feeding.

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

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

AMGEVITA® AND ME

WHAT DO I NEED TO TELL THE HEALTHCARE TEAM?

It is important to tell your healthcare team if you feel unwell (however small a problem it seems). They also need to know about any other drugs you may be taking, even herbal remedies, health supplements (including over the counter) or recreational drugs (in confidence).

You should always tell any other doctor or nurse looking after you for another condition/illness that you are being treated with AMGEVITA®.

WHAT SHOULD I TELL PEOPLE AT MY SCHOOL/ COLLEGE?

You may find it helpful to let your teachers at school/college know that you are being treated with AMGEVITA®, in case you need to miss school to go for treatment or for a check-up with the healthcare team.

Live vaccines (e.g. BCG) shouldn't be given while you are on AMGEVITA®. If you are offered a vaccine at school, check with the school nurse or your healthcare team if it's OK for you to have it.

It is important that you have had all your immunisations before starting AMGEVITA®, so please discuss immunisation with your family doctor, or nurse if you are unsure what you need to have.

SHOULD I TELL MY FRIENDS?

It is up to you what to tell your friends about your treatment and/or condition. Share your story when you feel ready to.

Talking to your friend(s) about your treatment and/or condition can be hard. There are ways to make it easier:

- Talk about how you feel
- Tell them what makes you sick
- Answer your friend's questions
- Have your parents or carer help you answer more difficult questions

GLOSSARY

WHAT DOES THAT WORD MEAN?

Antibodies – proteins found in the body that are part of the immune system. They bind to bacteria, viruses etc in the body and stop them from causing infection

Healthcare Team – All the healthcare professionals involved with your treatment, including consultants, doctors, and nurses

Inflammation – A localized physical condition in which a part of the body becomes reddened, swollen, hot, and often painful, like a reaction to injury or infection

Live vaccines – Vaccines work by using a small amount of an infectious organism (e.g. virus or bacteria) to stimulate the body to make antibodies to that agent. This means that when a vaccinated person meets the bacteria/virus, the immune system should recognise it and stop it from causing illness/infection

Protein – Are important components of every cell in the body. Your body uses protein to build and repair tissues and to make enzymes, hormones, and other body chemicals. Proteins are also an important building block of body tissues, such as bones, muscles, cartilage, skin, and blood

Side effects – unintended effects caused by medical treatment, that are different from the benefit of taking the medication

Subcutaneous – something applied under the skin

Tumour necrosis factor-alpha (TNF α) – A protein involved in inflammatory processes and in protecting the body from infection

Tuberculosis (TB) – A type of bacterial infection that mainly affects the lungs. It can be spread by coughs or sneezes from someone affected by the disease

AMGEN HOMECARE SUPPORT SERVICES

- We work with recognised homecare providers for convenient access to AMGEVITA® when your child needs 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 on 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 your child

MY MAIN CONTACT IS:

Phone: _____

Email: _____

MY SECOND CONTACT IS:

Phone: _____

Email: _____

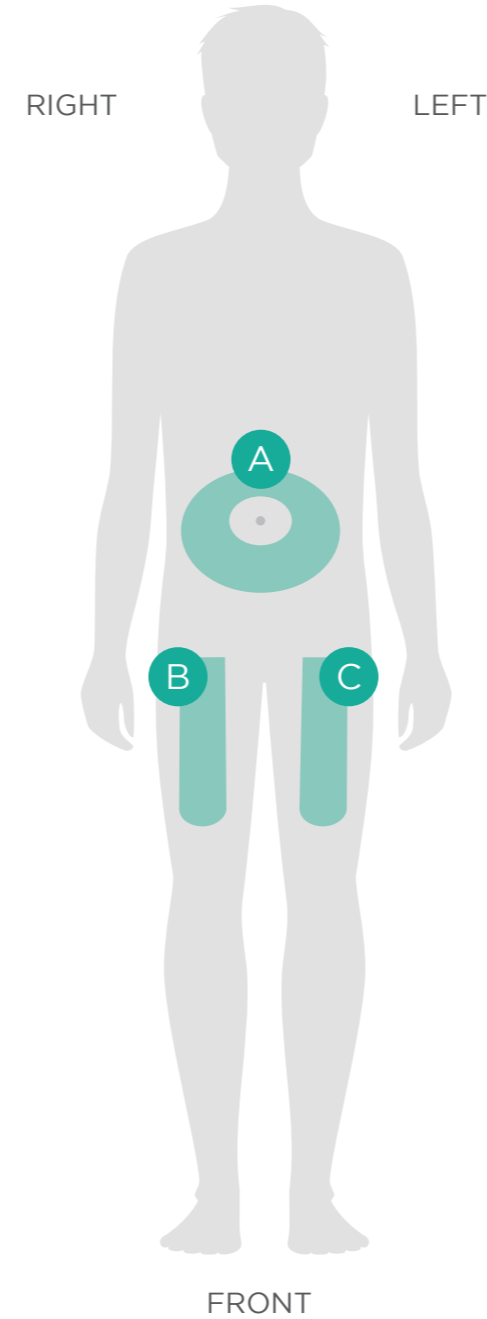
MY HOMECARE PROVIDER IS:

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

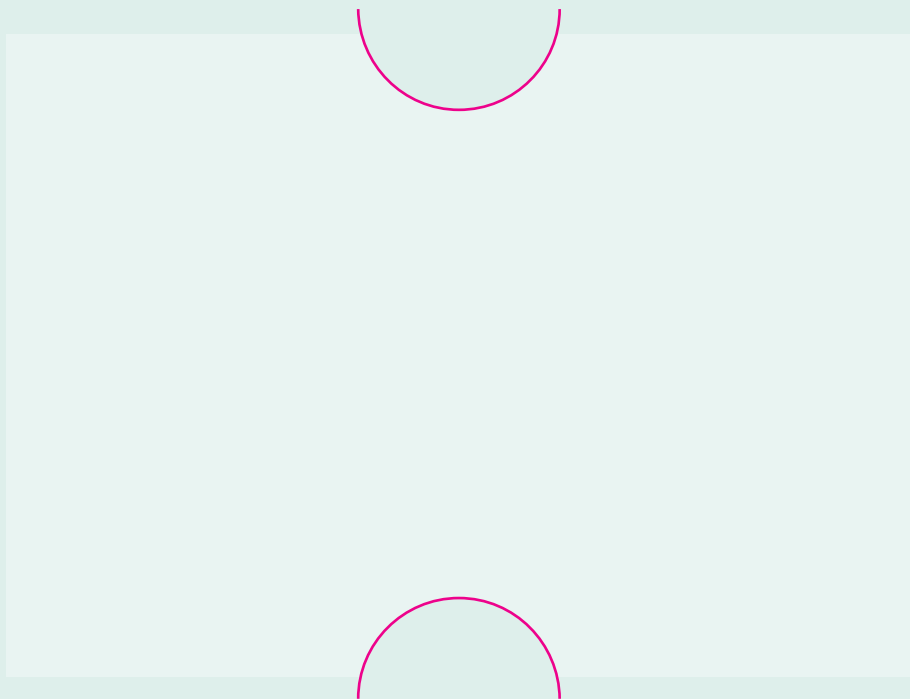
INJECTION SITES



NOTES

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 are taking AMGEVITA® and for 4 months after the last dose.



Learn more at
amgencare.co.uk

NI-501-1122-80004 [Northern Ireland]
Date of preparation: June 2023
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