



AMGEVITA[®] (adalimumab)

A GUIDE FOR PARENTS/CARERS OF CHILDREN BEING TREATED WITH AMGEVITA[®]

AmgenCare is a patient service provided by Amgen

**This booklet is only intended for parents or carers of children
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

WELCOME TO AMGEVITA®

Looking after a child with an inflammatory disease is not easy, but medication can help provide some relief for your child's symptoms. This guide is provided to help you to understand how to manage your child's treatment with AMGEVITA®.

- Please read both this patient booklet and the package leaflet that comes with your child's treatment pack. It contains full and detailed instructions on how to administer AMGEVITA®.
- 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
- You'll find a patient reminder card at the back of this booklet. Complete it and make sure your child carries it at all times. It contains important safety and medical information and contacts. In the event of an emergency, it will tell a healthcare professional that your child is taking AMGEVITA®
- This medicine has been prescribed for your child only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as your child

AMGEVITA® is a registered trademark of Amgen Inc.

The photos throughout this guide are posed by models.



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

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ABOUT AMGEVITA®

WHAT IS AMGEVITA®?

AMGEVITA® 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 child's symptoms.

AMGEVITA® helps to block the action of the protein TNF α 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.

ABOUT AMGEVITA®

WHY HAS MY SON/ DAUGHTER 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**
- **Uveitis**



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 the joints as 'alien'. This means the immune system will attack the 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 patients may suffer from pain in the bottoms of their feet, around the hips, knees or in their 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 their 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 5 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.

INJECTING AMGEVITA®

Your child's doctor or nurse will train you or your child on how to inject 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 contains either 20mg or 40mg of adalimumab and should be administered as often as directed by your child's doctor or nurse prescriber. Always follow your child's doctor or nurse's instructions on when to use AMGEVITA®. 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 your child have any side effects or issues with the pre-filled pen or pre-filled syringe.

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

Allergies

It is important that you tell your child's healthcare professional if he/she has any allergies.

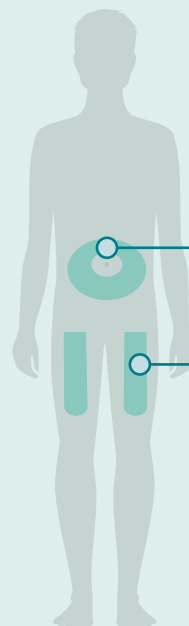
Amgen are no longer manufacturing the AMGEVITA® Sureclick® prefilled pen with latex, however there will still be a latex AMGEVITA® Sureclick® prefilled pen available until it is eventually removed from the pharmacy/dispensary supply chain.

IMPORTANT: If your child has a latex allergy please inform their prescriber, dispensing pharmacist and nurse so they can ensure your child is 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.

WHERE TO INJECT?



AMGEVITA® should be injected in your child's thigh or belly (except for a 2 inches/5 centimetres area around the button).

1 Belly

2 Thigh

You will need to clean the injection site with an alcohol wipe and let their skin dry. Do not touch this area again before injecting.

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

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

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

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

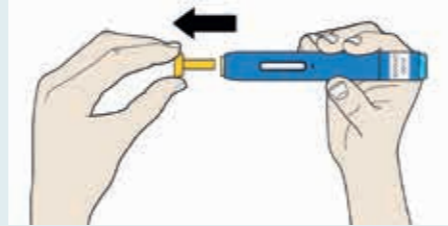
First wash your hands thoroughly with soap and water.

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.

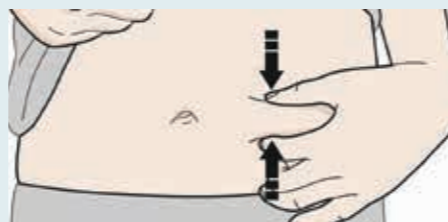
HOW TO INJECT

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



The stretch method

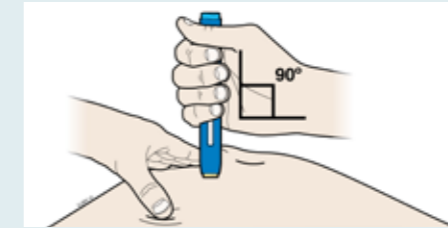
Stretch skin firmly by moving your thumb and fingers in the opposite direction, creating an area about 2 inches/ 5 centimetres wide.



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 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

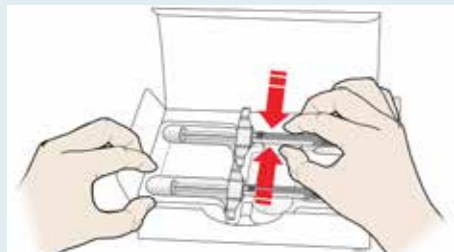
STEP 1: CHECKING THE SYRINGE

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.

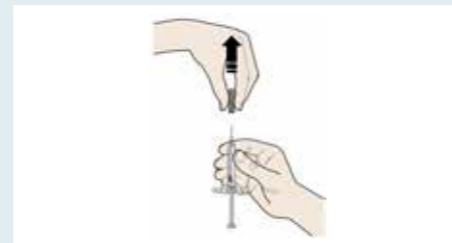
STEP 2: GETTING READY

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

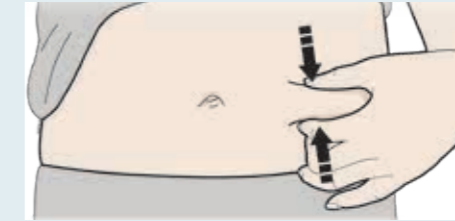


Pull the needle cap straight out and away from your body when you are ready to inject.

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

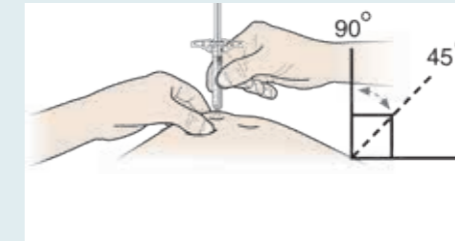
- ✗ Do not twist or bend the needle cap.
- ✗ Do not put the needle cap back onto the syringe.
- ✗ Do not remove the needle cap from the syringe until you are ready to inject.

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.

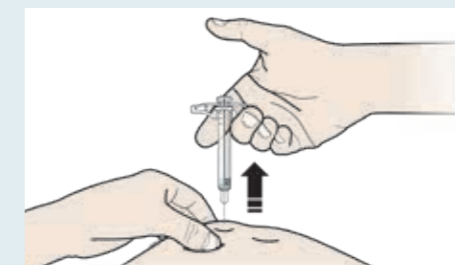


Hold the pinch. With the needle cap off, insert the pre-filled syringe into your skin at 45 to 90 degrees.

! 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 the 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



POSSIBLE SIDE EFFECTS

What to do if your child feels unwell

Like all medicines, AMGEVITA® can cause side effects, although not everyone gets them. Most side effects are mild or 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 child's nervous system.

Speak to your doctor or nurse about the pros and cons of your child 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. Your child will be screened for tuberculosis (TB) and other infectious diseases before starting treatment.

You will need to notify your child's healthcare team **immediately** if your child experiences any of the following signs of allergic reaction or heart failure:

- Severe rash, hives 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 child's doctor as soon as possible if you or your child 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.

A full list of side effects of AMGEVITA® are available in the Package Leaflet or on request from your child's healthcare team. It can also be found by searching for AMGEVITA® at:

<https://www.emcmedicines.com/en-gb/northernireland/>

Consult the healthcare team if your child is experiencing any new symptoms on AMGEVITA®.

What benefits can my child expect from AMGEVITA® and when?

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

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

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

FREQUENTLY ASKED QUESTIONS

Why does my child need to stay on treatment if they're feeling better?

Even if your child is feeling better after using AMGEVITA®, because their condition is long term and chronic, they need to continue with their treatment as instructed by your child's doctor.

What if my child misses a dose?

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

What if I accidentally give a dose too early?

Talk to your child's 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.

Can my child drive/ cycle/ scoot / operate machinery?

AMGEVITA® may have a minor influence on your child's 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.

What about travelling with my child's 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 child's nurse, doctor or pharmacist before you go away.

What if I leave my child's 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 my child avoid vaccinations with AMGEVITA®?

Certain vaccines may cause infections and should not be given while receiving AMGEVITA® (e.g. BCG). Please check with your child's doctor before they receive any vaccines. It is recommended that, if possible, children be brought up to date with all immunisations in agreement with current immunisation guidelines prior to initiating AMGEVITA® therapy.

What do I need to tell the healthcare team

It is important to tell your healthcare team any symptoms that your child is experiencing. Also tell the healthcare team if you are aware that your child is taking herbal remedies, over the counter medication or using recreational drugs.



What should my child tell people at their school/college?

Your child may find it helpful to let their teachers at school/college know that they are being treated with AMGEVITA®, in case they 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 your child is on AMGEVITA®. If your child is offered a vaccine at school, check with the school nurse or the healthcare team if it's ok for them to have it.

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



Should my child discuss their treatment/condition with their friends?

It is up to your child what they tell their friends about their treatment and/or condition. Your child should share their story when they feel ready to.

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

- Talk about how they feel
- Answer their friend's questions
- Tell them what makes your child sick
- Have you present to help them answer more difficult questions



Do I need to do anything if my child is sexually active?

If your daughter is sexually active, she should consider using adequate contraception to prevent pregnancy during treatment and for at least 5 months after the last dose. If your daughter thinks she's pregnant or is planning to have a baby, speak to your healthcare team, for advice about taking AMGEVITA®.

AMGEVITA® should only be used during a pregnancy if needed.

AMGEVITA® can be used during breast-feeding.

If your daughter receives AMGEVITA during pregnancy, her baby may have a higher risk for getting an infection.

If your daughter receives AMGEVITA whilst pregnant, it is important you tell the baby's healthcare team before the baby receives any vaccines.

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: _____

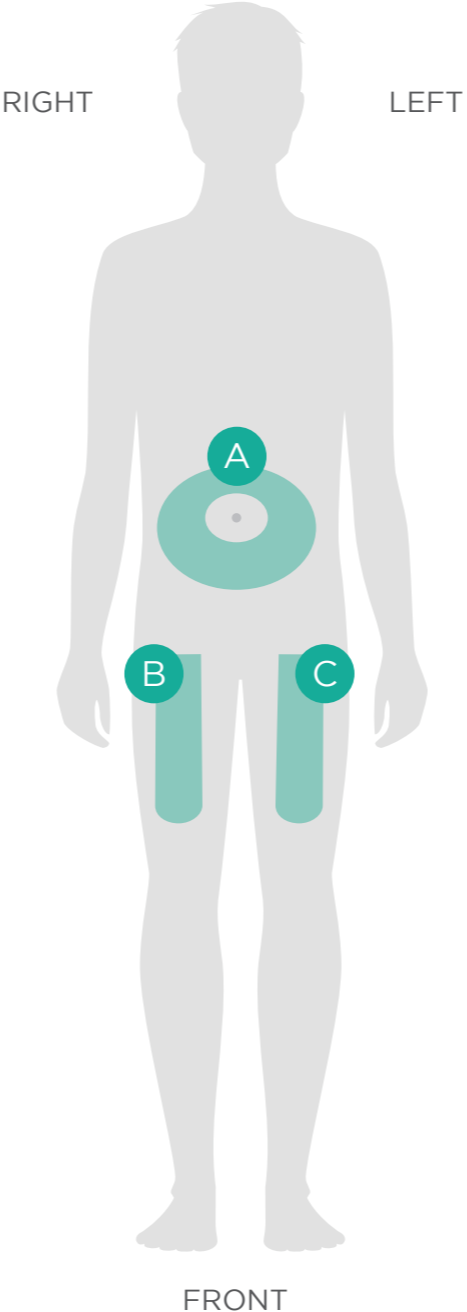
MY HOMECARE PROVIDER IS:

INJECTION TRACKING CHART TO SHARE WITH YOUR CHILD'S NURSE

This chart is to help you to track injection sites on your child's body.
Make a note of the expiry and batch number in case your child experiences any issues.

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

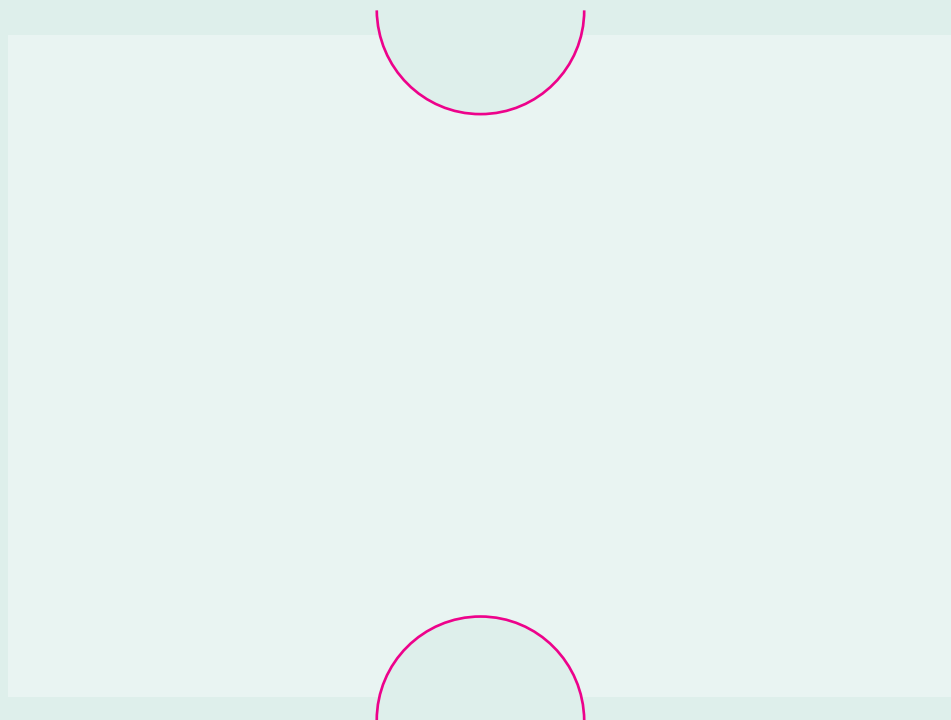
INJECTION SITES



NOTES:

PATIENT REMINDER CARD

Make sure your child has the patient reminder card about their person so that they've always got it with them while taking AMGEVITA® and for 4 months after the last dose.



PLEASE READ THE PATIENT INFORMATION LEAFLET THAT CAME WITH YOUR CHILD'S TREATMENT

AMGEN®

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Learn more at
amgencare.co.uk

