READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PATIENT MEDICATION INFORMATION

PrAMGEVITA®

pronounced *am je vee' tah*

adalimumab injection

Single-Use Prefilled Syringe

Read this carefully before you start taking AMGEVITA and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about AMGEVITA.

AMGEVITA is a biosimilar biologic drug (biosimilar) to the reference biologic drug HUMIRA®. A biosimilar is authorized based on its similarity to a reference biologic drug already authorized for sale.

Serious Warnings and Precautions

Any medicine can have side effects. Like all medicines that affect your immune system, AMGEVITA can cause serious side effects. The possible serious side effects include:

- **Allergic reactions:** If you/your child develop a severe rash, swollen face or difficulty breathing while taking AMGEVITA call your doctor right away.
- **Hepatosplenic T-cell lymphoma:** Very rare reports of hepatosplenic T-cell lymphoma (HSTCL), a rare serious lymphoma that is often fatal, have been identified in patients treated with adalimumab. Most patients had also been treated with other medications for Crohn's disease and the majority were in adolescent and young adult males. The link between HSTCL and adalimumab is not clear.
- **Other cancer:** There have been very rare cases of certain kinds of cancer in patients taking adalimumab or other TNF-blockers. Some patients receiving adalimumab have developed types of cancer called non-melanoma skin cancer. Tell your doctor if you have a bump or open sore that does not heal. People with more serious rheumatoid arthritis that have had the disease for a long time may have a higher than average risk of getting a kind of cancer that affects the lymph system, called lymphoma. If you/your child take AMGEVITA or other TNF-blockers, your/your child's risk may increase. There have been cases of lymphoma and other cancers, including unusual types, in children, adolescents and young adults taking TNF-blocking agents, including adalimumab, which sometimes resulted in death. For children and adults taking TNF-blocker medicines, the chances of developing lymphoma or other cancers may increase.
- **Lupus-like symptoms:** Some patients have developed lupus-like symptoms that got better after their treatment was stopped. If you/your child have chest pains that do not go away, shortness of breath, joint pain or a rash on your cheeks or arms that gets worse in the sun, call your doctor right away. Your/your child's doctor may decide to stop your treatment.
- **Nervous system diseases:** There have been rare cases of disorders that affect the nervous system of people taking adalimumab or other TNF-blockers. Signs that you/your child could be experiencing a problem affecting your nervous system include: numbness or tingling, problems with your vision, weakness in your legs, and dizziness.

- **Serious infections:** There have been rare cases where patients taking adalimumab or other TNF-blocking agents have developed serious infections. Some of these cases have been life-threatening. Such infections include tuberculosis, infections caused by bacteria or fungi, and bacterial infections that have spread throughout the body (sepsis). Infection causes include tuberculosis, legionellosis (a serious form of bacterial pneumonia), listeriosis (an infection that usually develops after eating food contaminated by bacteria called listeria), and very rare cases of hepatitis B infection relapse.
- **Blood problems:** In some instances, patients treated with TNF-blocking agents may develop low blood counts, such as anemia (low red blood cells) or low platelets. If you/your child develop symptoms such as persistent fever, bleeding, or bruising, you should contact your/your child's doctor right away.

What is AMGEVITA used for?

AMGEVITA treatment should be started and supervised by specialist physicians experienced in the diagnosis and treatment of rheumatoid arthritis (RA), polyarticular juvenile idiopathic arthritis (JIA), psoriatic arthritis (PsA), ankylosing spondylitis (AS), adult and pediatric Crohn's disease (CD), ulcerative colitis (UC), adult and adolescent hidradenitis suppurativa (HS), psoriasis (Ps) or adult and pediatric uveitis, and familiar with the AMGEVITA efficacy and safety profile.

AMGEVITA is a medicine that is used in:

- adults with rheumatoid arthritis which is an inflammatory disease of the joints.
- patients 2 years of age and older who have polyarticular juvenile idiopathic arthritis.
- adults with psoriatic arthritis, which is an inflammatory disease of the joints and skin.
- adults with ankylosing spondylitis, which is a form of arthritis.
- adults with Crohn's disease, which is an inflammatory disease of the digestive tract.
- children 13 to 17 years weighing ≥ 40 kg who have severe Crohn's disease or who have Crohn's disease which has not responded to other usual treatments.
- adults with ulcerative colitis, which is an inflammatory disease of the bowel (colon).
- adults or adolescents (12 to 17 years of age, weighing ≥ 30 kg) with moderate to severe hidradenitis suppurativa (HS) who have not responded to antibiotics. HS is a painful, progressive, chronic inflammatory skin disease that causes nodules, abscesses, sinus tracts and fistulas under the breasts, underarms, buttocks and groin.
- adults with psoriasis, which is an inflammatory disease of the skin. Your doctor prescribed AMGEVITA to reduce the signs and symptoms of your plaque psoriasis.
- adults with uveitis, which is an inflammatory disease of the eye.
- Children with chronic non-infectious uveitis from 2 years of age with inflammation affecting the front of the eye.

Patients with rheumatoid arthritis, polyarticular juvenile idiopathic arthritis, psoriatic arthritis, ankylosing spondylitis, hidradenitis suppurativa, psoriasis, or uveitis may be given other medicines for their disease before they are given AMGEVITA. If you have ulcerative colitis or you/your child have Crohn's disease, you/your child will first be given other medicines. If you/your child do not respond well enough to these medicines, you/your child will be given AMGEVITA to reduce the signs and symptoms of your/your child's disease.

How does AMGEVITA work?

AMGEVITA is a fully human monoclonal antibody produced by cultured cells. Monoclonal antibodies are proteins that recognize and bind to other unique proteins. AMGEVITA binds to a specific protein called TNF-alpha (also known as tumour necrosis factor). People with rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, Crohn's disease, ulcerative colitis, hidradenitis suppurativa, or psoriasis have too much of TNF-alpha in their bodies. The extra TNF-alpha in your/your child's body can attack normal healthy body tissues and cause inflammation, especially in the tissues of your bones, cartilage, joints and digestive tract. By binding to TNF-alpha, AMGEVITA decreases the inflammation process of these diseases.

AMGEVITA helps reduce the signs and symptoms of rheumatoid arthritis, polyarticular juvenile idiopathic arthritis and psoriatic arthritis (such as pain and swollen joints), may help improve your/your child's ability to perform daily activities (such as getting dressed, walking and climbing stairs), and may help prevent further damage to your/your child's bones and joints. In addition, AMGEVITA helps reduce the signs and symptoms of ankylosing spondylitis (back pain and morning stiffness), and adult and pediatric Crohn's disease or ulcerative colitis (abdominal pain and diarrhea). AMGEVITA may also help normalize childhood growth and pubertal development, and improve the quality of life in children who have Crohn's disease (such as body image, functional and social skills, and emotional health). AMGEVITA may help improve the work productivity and activity impairment in caregivers of children with Crohn's disease.

AMGEVITA is also used to treat inflammatory lesions (nodules and abscesses) in adult and adolescents (12 to 17 years of age, weighing ≥ 30 kg) with hidradenitis suppurativa.

AMGEVITA also helps reduce the signs and symptoms of psoriasis (such as pain, itching and scaly patches on skin).

AMGEVITA helps control uveitis by reducing the risk of inflammation and loss of vision in adult and pediatric patients.

AMGEVITA, however, can also lower your/your child's body's ability to fight infections. Taking AMGEVITA can make you/your child more prone to getting infections or make any infection you/your child have worse.

What are the ingredients in AMGEVITA?

The active substance is adalimumab.

- Each 0.8 mL prefilled syringe contains 40 mg of adalimumab (50 mg/mL) or 0.4 mL prefilled syringe contains 20 mg of adalimumab (50 mg/mL)

The other ingredients are glacial acetic acid, polysorbate 80, sodium hydroxide, sucrose and water for injection.

AMGEVITA comes in the following dosage forms:

AMGEVITA is available in the presentations listed below. Your/your child's doctor will prescribe the type that is best for you/your child.

- 40 mg/0.8 mL (50 mg/mL) or 20 mg/0.4 mL (50 mg/mL) single-use prefilled syringe
- 40 mg/0.8 mL (50 mg/mL) single-use prefilled autoinjector (SureClick®)

Do not use AMGEVITA if you/your child:

- have an allergy to any of the ingredients in AMGEVITA (see **What are the ingredients in AMGEVITA?** section).
- have a serious infection such as tuberculosis, infections caused by bacteria or fungi, and bacterial infections that have spread throughout the body (sepsis).
- have moderate to severe heart failure (NYHA class III/IV).

To help avoid effects and ensure proper use, talk to your/your child's healthcare professional before you/your child take AMGEVITA. Talk about any health conditions or problems you/your child may have, including if you/your child:

- have or have had any kind of infection including an infection that is in only one place in your body (such as an open cut or sore), or an infection that is in your whole body (such as the flu). Having an infection could put you/your child at risk for serious side effects from AMGEVITA. If you are unsure, ask your/your child's doctor.
- have a history of infections that keep coming back or other conditions that might increase your/your child's risk of infections, including fungal infections.
- have ever had tuberculosis, or if you/your child have been in close contact with someone who has had tuberculosis. If you/your child develop any of the symptoms of tuberculosis (a dry cough that doesn't go away, weight loss, fever, night sweats) call your/your child's doctor right away. Your/your child's doctor will need to examine you/your child for tuberculosis and perform a skin test.
- resided or traveled to areas where there is a greater risk for certain kinds of infections such as tuberculosis, histoplasmosis, coccidioidomycosis, blastomycosis, or parasitic infections. These infections are caused by a bacteria or a fungus that can affect the lungs or other parts of your/your child's body. If you/your child take AMGEVITA these may become active or more severe. If you/your child don't know if you have lived in or travelled to an area where these infections are common, ask your/your child's doctor.
- have ever had liver injury or hepatitis B virus infection or are at risk of developing this infection. Signs and symptoms include the following: yellowing of the skin or eyes (jaundice), feeling of sickness, tiredness, loss of appetite, joint pain, fever, dark brown-coloured urine, vomiting, and abdominal pain. If you/your child experience any of these signs and symptoms, contact your/your child's doctor immediately. These symptoms may occur several months after starting therapy with AMGEVITA.
- experience any numbness or tingling or have ever had a disease that affects your nervous system like multiple sclerosis or Guillain-Barré syndrome.
- have or have had heart failure.
- are scheduled to have major surgery or dental procedures.
- are scheduled to be vaccinated for anything. It is recommended that pediatric Crohn's disease patients, if possible, be brought up to date with all immunizations according to current guidelines before starting AMGEVITA.

- are taking other medicines for your rheumatoid arthritis, polyarticular juvenile idiopathic arthritis, psoriatic arthritis, ankylosing spondylitis, Crohn's disease, psoriasis, or other conditions. You/your child can take other medicines provided your doctor has prescribed them or has told you it is acceptable to take them while you are taking AMGEVITA. It is important that you tell your/your child's doctor about any other medicines you/your child are taking for other conditions (for example, high blood pressure medicine) before you/your child start taking AMGEVITA.
- are taking other medicines for you/your child's Crohn's disease or other conditions. You/your child can take other medicines provided the doctor has prescribed them or has told you it is acceptable that you/your child takes them while he/she is taking AMGEVITA. It is important that you tell the doctor about any other medicines you/your child are taking for other conditions before you/your child start taking AMGEVITA.
- are taking any over-the-counter drugs, herbal medicines and vitamin and mineral supplements.
- are pregnant or could become pregnant.
- are breast-feeding or plan to breast-feed.

Other warnings you should know about:

Before starting, during and after treatment with AMGEVITA, you or your child should be checked for active or inactive tuberculosis infection with a tuberculin skin test.

If you/your child received AMGEVITA while pregnant, your/her baby may be at higher risk for getting an infection for up to approximately five months after the last dose of AMGEVITA received during pregnancy. It is important that your/her baby's doctors and other healthcare professionals know about your/her AMGEVITA use during pregnancy so they can decide when your/her baby should receive any vaccine.

Tell your healthcare professional about all the medications you take, including any drugs, vitamins, minerals, natural supplements, or alternative medicines.

The following may interact with AMGEVITA:

- other TNF-blockers such as Enbrel®, Remicade®, Cimzia®, or Simponi®
- abatacept (Orenica®)
- anakinra (Kineret®)

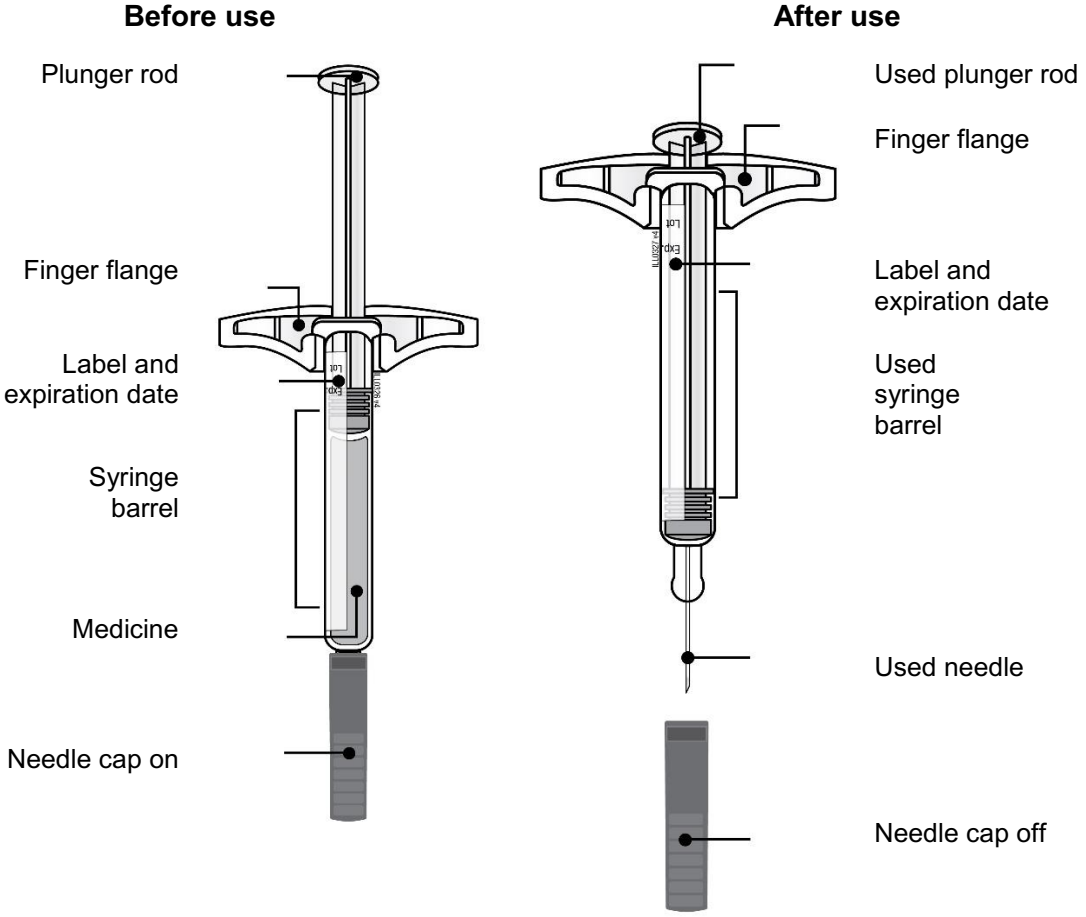
How to use AMGEVITA Single-use Prefilled Syringe:

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

AMGEVITA Single-use Prefilled Syringe

The following instructions are for preparing and giving an injection of AMGEVITA using a single-use prefilled syringe.

Guide to parts



Important: Needle is inside

Important

Before you use a single-use AMGEVITA prefilled syringe, read this important information:

Storing your AMGEVITA prefilled syringe

- Keep the AMGEVITA prefilled syringe out of the reach of children.
- Keep the AMGEVITA prefilled syringe in the original carton to protect from light or physical damage.
- The AMGEVITA prefilled syringe should be kept in the refrigerator between 2°C to 8°C.

- If needed, you may store the AMGEVITA prefilled syringe at room temperature at 20°C to 25°C for up to 14 days. Throw away AMGEVITA that has been stored at room temperature after 14 days.
- **Do not** store the AMGEVITA prefilled syringe in extreme heat or cold. For example, avoid storing in your vehicle's glove box or trunk.
- **Do not** freeze.

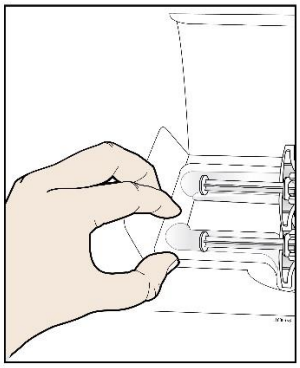
Using your AMGEVITA prefilled syringe

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

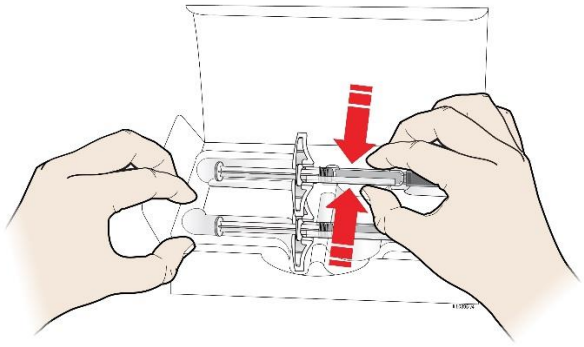
- **Do not** use an AMGEVITA prefilled syringe after the expiration date on the label.
- **Do not** shake the AMGEVITA prefilled syringe.
- **Do not** remove the needle cap from the AMGEVITA prefilled syringe until you are ready to inject.
- **Do not** use the AMGEVITA prefilled syringe if it has been frozen.
- **Do not** use the AMGEVITA prefilled syringe if it has been dropped on a hard surface. Part of the AMGEVITA prefilled syringe may be broken even if you cannot see the break. Use a new AMGEVITA prefilled syringe and call 1-866-502-6436.
- For more information or help, call 1-866-502-6436.

Step 1: Prepare

A. Remove the number of AMGEVITA prefilled syringes you need from the package. Grab the syringe barrel to remove the syringe from the tray.



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



Grab Here

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

For safety reasons:

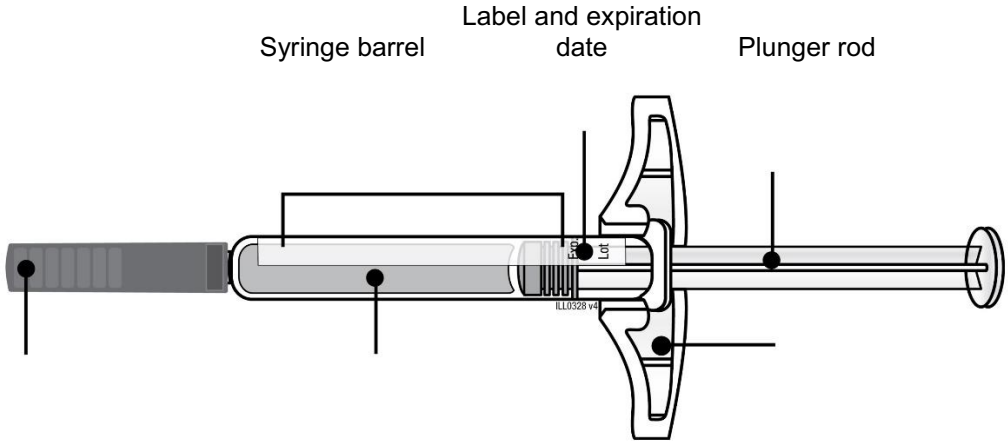
- **Do not** grasp the plunger rod.
- **Do not** grasp the needle cap.
- **Do not** remove the needle cap until you are ready to inject.
- **Do not** remove the finger flange. This is part of the syringe.

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

- **Do not** put the syringe back in the refrigerator once it has reached room temperature.
- **Do not** try to warm the syringe by using a heat source such as hot water or microwave.
- **Do not** leave the syringe in direct sunlight.
- **Do not** shake the syringe.

Important: Always hold the prefilled syringe by the syringe barrel.

B. Inspect the AMGEVITA prefilled syringe.



Always hold the syringe by the syringe barrel.

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

Do not use the prefilled syringe if:

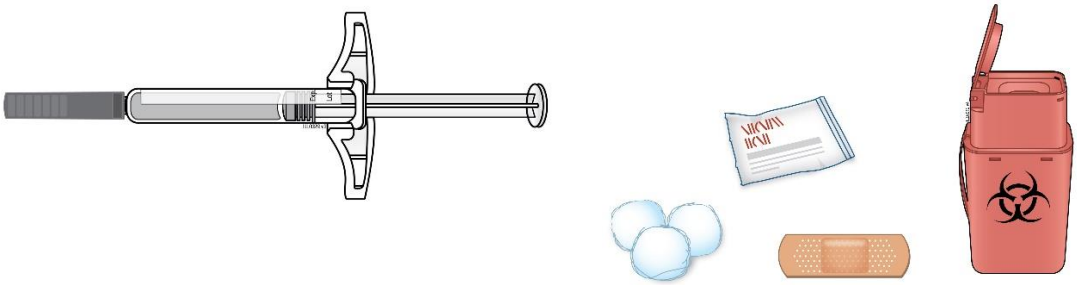
- the medicine is cloudy or discoloured, or contains flakes, or particles.
- any part appears cracked or broken.
- the needle cap is missing or not securely attached.
- the expiration date printed on the label has passed.

In any above cases, use a new prefilled syringe and call 1-866-502-6436.

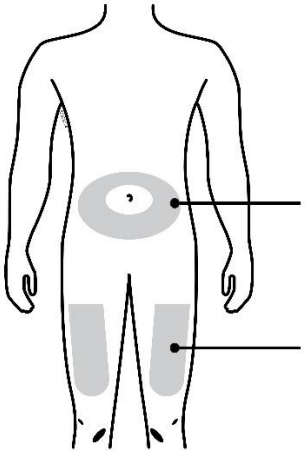
C. Gather all materials needed for your injection(s).

Wash your hands thoroughly with soap and water. On a clean, well-lit, flat work surface, place:

- New prefilled syringe(s)
- Alcohol wipes
- Cotton ball or gauze pad
- Adhesive bandage
- Sharps disposal container



D. Prepare and clean your injection site(s).



Stomach area (abdomen)

Thigh

You can use:

- Your thigh
- Stomach area (abdomen), except for the **5** centimetre **(2** inch) area around the belly button.

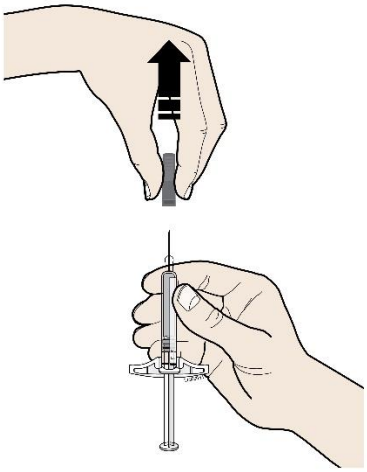
Clean the injection site with an alcohol wipe. Let your skin dry.

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

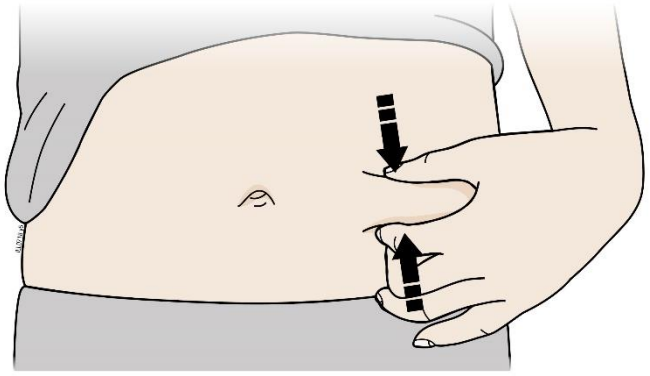


It is normal to see a drop of liquid at the end of the needle.

- **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.

Important: Throw the needle cap into the sharps disposal container provided.

F. Pinch your injection site to create a firm surface.

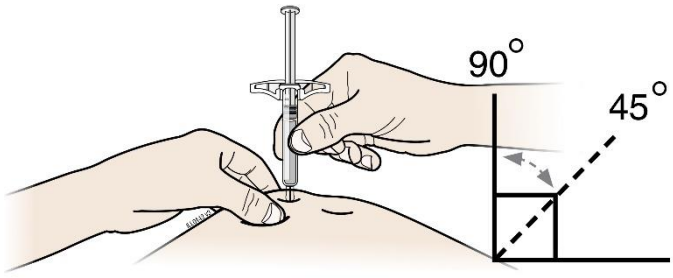


Pinch the skin firmly between your thumb and fingers, creating an area about **5** centimetres (**2** inches) wide.

Important: Keep skin pinched while injecting.

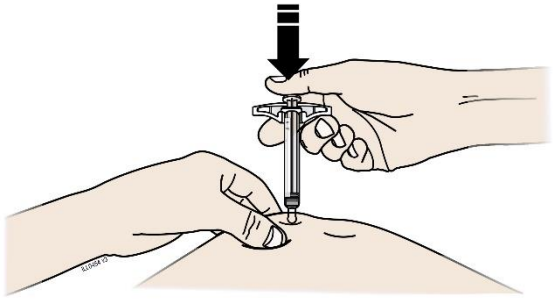
Step 3: Inject

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

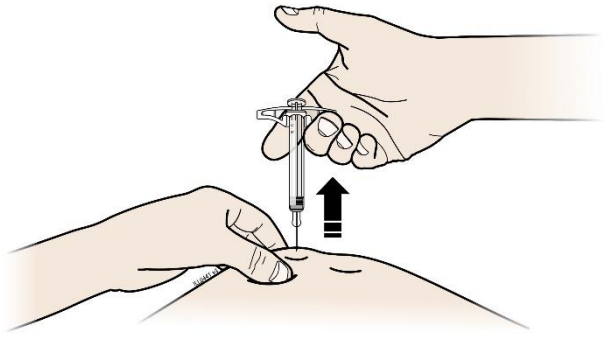


Do not place your finger on the plunger rod while inserting the needle.

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



I. When done, **release** your thumb, and gently lift the syringe off skin.



Step 4: Finish

J. Discard the used syringe and the needle cap in a sharps disposal container.

- Put the used syringe in a sharps disposal container immediately after use. **Do not** throw away (dispose of) the syringe in your household trash.
- Talk with your doctor or pharmacist about proper disposal. There may be local guidelines for disposal.
- If you do not have a sharps disposal container, you may use a household container that is:
  - made of a heavy-duty plastic,
  - can be closed with a tight-fitting, puncture-resistant lid, without sharps being able to come out,
  - upright and stable during use,
  - leak-resistant, and
  - properly labeled to warn of hazardous waste inside the container.
- When your sharps disposal container is almost full, you will need to follow your community guidelines for the right way to dispose of your sharps disposal container. There may be provincial or local laws about how you should throw away used needles and syringes.
- **Important:** Always keep the syringe and the sharps disposal container out of the reach of children.
- **Do not** reuse the syringe.
- **Do not** use any medicine that is left in the used syringe.
- **Do not** recycle the syringe or the sharps disposal container or throw it into household trash.

K. 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 an adhesive bandage if needed.

Usual Dose:

Adults with Rheumatoid Arthritis, Psoriatic Arthritis or Ankylosing Spondylitis:

- The recommended dose is 40 mg administered every other week as a subcutaneous injection.

Patients, aged 2 years and older, with polyarticular juvenile idiopathic arthritis:

- Weighing 10 kg to less than 30 kg: The recommended dose of AMGEVITA is 20 mg every other week.
- Weighing 30 kg or more: The recommended dose of AMGEVITA is 40 mg every other week.

For patients who do not require a full 40 mg dose of AMGEVITA, a 20 mg pre-filled syringe is also available.

Adults with Crohn's Disease or Ulcerative Colitis:

- The recommended induction dose is 160 mg at Week 0 (dose can be administered as four injections in one day or as two injections per day for two consecutive days), followed by 80 mg at Week 2.
- The recommended maintenance dose regimen is 40 mg every other week beginning at Week 4.

Children, 13 to 17 years of age weighing ≥ 40 kg, with Crohn's disease:

- The recommended dose is 160 mg initially at Week 0 (given as four 40 mg injections in one day, or as two 40 mg injections per day for two consecutive days), followed by 80 mg at Week 2 (given as two 40 mg injections). At Week 4, your child will begin a maintenance dose of 20 mg every other week. Depending on your child's response, the doctor may increase the dose to 40 mg every other week (given as one 40 mg injection).

For children who do not require a full 40 mg dose of AMGEVITA, a 20 mg pre-filled syringe is also available.

Adults with Hidradenitis Suppurativa:

- The recommended initial dose is 160 mg, followed by 80 mg two weeks later. The first dose of 160 mg can be administered as four injections in one day or as two injections per day for two consecutive days. The second dose of 80 mg is given as two 40 mg injections in one day.

The recommended maintenance dose regimen is 40 mg every week beginning four weeks after the initial dose

Adolescents, 12 to 17 years of age weighing ≥ 30 kg, with Hidradenitis Suppurativa:

- The recommended initial dose is 80 mg administered by subcutaneous injection, followed by 40 mg every other week starting one week later. Depending on your/your child's response, the doctor may increase the dose to 40 mg every week.

Adults with Psoriasis or Uveitis:

- The recommended dose is an initial dose of 80 mg, followed by 40 mg given every other week starting one week after the initial dose.

Children, from 2 years of age, with Uveitis:

- weighing less than 30 kg: the usual dose of AMGEVITA is 20 mg every other week with methotrexate. Your child's doctor may also prescribe an initial dose of 40 mg to be administered one week prior to the start of the usual dose if your child is older than 6 years of age.
- weighing 30 kg or more: the usual dose of AMGEVITA is 40 mg every other week with methotrexate. Your child's doctor may also prescribe an initial dose of 80 mg to be administered one week prior to the start of the usual dose.

For children who do not require a full 40 mg dose of AMGEVITA, a 20 mg pre-filled syringe is also available

Overdose:

If you think you/your child have used too much AMGEVITA, contact your/your child's healthcare professional, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

Missed Dose:

If you forget to give yourself or your child an injection, you should inject the missed dose of AMGEVITA as soon as you remember. Then administer the next dose as you would have on the originally scheduled date.

What are possible side effects from using AMGEVITA:

These are not all the possible side effects you may feel when taking AMGEVITA. If you experience any side effects not listed here, contact your healthcare professional. Please also see **Warnings and Precautions**.

Tell your/your child's doctor immediately if you/your child experience any of the following:

- severe rash, hives or other signs of allergic reaction
- swollen face, hands, feet
- trouble breathing, swallowing
- sudden weight gain (this is possibly indicative of new or worsening heart failure)
- bruising or bleeding very easily, looking very pale; this could mean a blood problem such as low red blood cells (anemia) or low platelets.

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

- signs of infection such as fever, malaise, wounds, dental problems, burning on urination
- feeling weak or tired
- coughing
- tingling
- numbness
- double vision
- arm or leg weakness

- arm or leg pain, swelling or redness
- bump or open sore that does not heal
- red scaly patches or raised bumps that are filled with pus; this could be new or worsening hidradenitis suppurativa, new or worsening psoriasis or a skin infection
- alopecia (loss of hair)
- changes in the colour of the skin
- changes in the colour of your urine (dark or red)
- worsening of the appearance of a scar
- night sweats
- weight loss
- pain in the abdomen or chest

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
VERY COMMON			
Injection site reaction		✓	
COMMON			
Cough and cold symptoms, including sore throat		✓	
Headache	✓		
Rash		✓	
Nausea		✓	
Pneumonia		✓	✓
Fever		✓	
Abdominal pain	✓		
UNCOMMON			
Tuberculosis		✓	✓
Other serious infections		✓	✓
Nerve disorders		✓	✓
Appendicitis		✓	✓
Blood clots: abdominal pain, chest pain, leg or arm pain with redness and swelling		✓	✓
Bladder infection (painful urination)		✓	✓

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
Hepatitis [jaundice (yellow skin, dark urine), abdominal pain, tiredness]		✓	✓

If you have troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

Reporting Side Effects
You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

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 to 8°C). Do not freeze.

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

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

Keep out of reach and sight of children.

If you want more information about AMGEVITA:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website; the manufacturer's website www.amgen.ca, or by calling 1-866-502-6436.

This leaflet was prepared by Amgen Canada Inc.

Last Revised: July 9, 2021

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PATIENT MEDICATION INFORMATION

PrAMGEVITA®

pronounced *am je vee' tah*

adalimumab injection

Single-Use Prefilled Sureclick® Autoinjector

Read this carefully before you start taking AMGEVITA and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about AMGEVITA.

AMGEVITA is a biosimilar biologic drug (biosimilar) to the reference biologic drug HUMIRA®. A biosimilar is authorized based on its similarity to a reference biologic drug already authorized for sale.

Serious Warnings and Precautions

Any medicine can have side effects. Like all medicines that affect your immune system, AMGEVITA can cause serious side effects. The possible serious side effects include:

- **Allergic reactions:** If you/your child develop a severe rash, swollen face or difficulty breathing while taking AMGEVITA call your doctor right away.
- **Hepatosplenic T-cell lymphoma:** Very rare reports of hepatosplenic T-cell lymphoma (HSTCL), a rare serious lymphoma that is often fatal, have been identified in patients treated with adalimumab. Most patients had also been treated with other medications for Crohn's disease and the majority were in adolescent and young adult males. The link between HSTCL and adalimumab is not clear.
- **Other cancer:** There have been very rare cases of certain kinds of cancer in patients taking adalimumab or other TNF-blockers. Some patients receiving adalimumab have developed types of cancer called non-melanoma skin cancer. Tell your doctor if you have a bump or open sore that does not heal. People with more serious rheumatoid arthritis that have had the disease for a long time may have a higher than average risk of getting a kind of cancer that affects the lymph system, called lymphoma. If you/your child take AMGEVITA or other TNF-blockers, your/your child's risk may increase. There have been cases of lymphoma and other cancers, including unusual types, in children, adolescents and young adults taking TNF-blocking agents, including adalimumab, which sometimes resulted in death. For children and adults taking TNF-blocker medicines, the chances of developing lymphoma or other cancers may increase.
- **Lupus-like symptoms:** Some patients have developed lupus-like symptoms that got better after their treatment was stopped. If you/your child have chest pains that do not go away, shortness of breath, joint pain or a rash on your cheeks or arms that gets worse in the sun, call your doctor right away. Your/your child's doctor may decide to stop your treatment.

- **Nervous system diseases:** There have been rare cases of disorders that affect the nervous system of people taking adalimumab or other TNF-blockers. Signs that you/your child could be experiencing a problem affecting your nervous system include: numbness or tingling, problems with your vision, weakness in your legs, and dizziness.
- **Serious infections:** There have been rare cases where patients taking adalimumab or other TNF-blocking agents have developed serious infections. Some of these cases have been life-threatening. Such infections include tuberculosis, infections caused by bacteria or fungi, and bacterial infections that have spread throughout the body (sepsis). Infection causes include tuberculosis, legionellosis (a serious form of bacterial pneumonia), listeriosis (an infection that usually develops after eating food contaminated by bacteria called listeria), and very rare cases of hepatitis B infection relapse.
- **Blood problems:** In some instances, patients treated with TNF-blocking agents may develop low blood counts, such as anemia (low red blood cells) or low platelets. If you/your child develop symptoms such as persistent fever, bleeding, or bruising, you should contact your/your child's doctor right away.

What is AMGEVITA used for?

AMGEVITA treatment should be started and supervised by specialist physicians experienced in the diagnosis and treatment of rheumatoid arthritis (RA), polyarticular juvenile idiopathic arthritis (JIA), psoriatic arthritis (PsA), ankylosing spondylitis (AS), adult and pediatric Crohn's disease (CD), ulcerative colitis (UC), adult and adolescent hidradenitis suppurativa (HS), psoriasis (Ps) or adult and pediatric uveitis, and familiar with the AMGEVITA efficacy and safety profile.

AMGEVITA is a medicine that is used in:

- adults with rheumatoid arthritis which is an inflammatory disease of the joints.
- patients 2 years of age and older who have polyarticular juvenile idiopathic arthritis.
- adults with psoriatic arthritis, which is an inflammatory disease of the joints and skin.
- adults with ankylosing spondylitis, which is a form of arthritis.
- adults with Crohn's disease, which is an inflammatory disease of the digestive tract.
- children 13 to 17 years weighing ≥ 40 kg who have severe Crohn's disease or who have Crohn's disease which has not responded to other usual treatments.
- adults with ulcerative colitis, which is an inflammatory disease of the bowel (colon).
- adults or adolescents (12 to 17 years of age, weighing ≥ 30 kg) with moderate to severe hidradenitis suppurativa (HS) who have not responded to antibiotics. HS is a painful, progressive, chronic inflammatory skin disease that causes nodules, abscesses, sinus tracts and fistulas under the breasts, underarms, buttocks and groin.
- adults with psoriasis, which is an inflammatory disease of the skin. Your doctor prescribed AMGEVITA to reduce the signs and symptoms of your plaque psoriasis.
- adults with uveitis, which is an inflammatory disease of the eye.
- Children with chronic non-infectious uveitis from 2 years of age with inflammation affecting the front of the eye.

Patients with rheumatoid arthritis, polyarticular juvenile idiopathic arthritis, psoriatic arthritis, ankylosing spondylitis, hidradenitis suppurativa, psoriasis, or uveitis may be given other medicines for their disease before they are given AMGEVITA. If you have ulcerative colitis or you/your child have Crohn's disease, you/your child will first be given other medicines. If you/your child do not respond well enough to these medicines, you/your child will be given AMGEVITA to reduce the signs and symptoms of your/your child's disease.

How does AMGEVITA work?

AMGEVITA is a fully human monoclonal antibody produced by cultured cells. Monoclonal antibodies are proteins that recognize and bind to other unique proteins. AMGEVITA binds to a specific protein called TNF-alpha (also known as tumour necrosis factor). People with rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, Crohn's disease, ulcerative colitis, hidradenitis suppurativa, or psoriasis have too much of TNF-alpha in their bodies. The extra TNF-alpha in your/your child's body can attack normal healthy body tissues and cause inflammation, especially in the tissues of your bones, cartilage, joints and digestive tract. By binding to TNF-alpha, AMGEVITA decreases the inflammation process of these diseases.

AMGEVITA helps reduce the signs and symptoms of rheumatoid arthritis, polyarticular juvenile idiopathic arthritis and psoriatic arthritis (such as pain and swollen joints), may help improve your/your child's ability to perform daily activities (such as getting dressed, walking and climbing stairs), and may help prevent further damage to your/your child's bones and joints. In addition, AMGEVITA helps reduce the signs and symptoms of ankylosing spondylitis (back pain and morning stiffness), and adult and pediatric Crohn's disease or ulcerative colitis (abdominal pain and diarrhea). AMGEVITA may also help normalize childhood growth and pubertal development, and improve the quality of life in children who have Crohn's disease (such as body image, functional and social skills, and emotional health). AMGEVITA may help improve the work productivity and activity impairment in caregivers of children with Crohn's disease.

AMGEVITA is also used to treat inflammatory lesions (nodules and abscesses) in adult and adolescents (12 to 17 years of age, weighing ≥ 30 kg) with hidradenitis suppurativa.

AMGEVITA also helps reduce the signs and symptoms of psoriasis (such as pain, itching and scaly patches on skin).

AMGEVITA helps control uveitis by reducing the risk of inflammation and loss of vision in adult and pediatric patients.

AMGEVITA, however, can also lower your/your child's body's ability to fight infections. Taking AMGEVITA can make you/your child more prone to getting infections or make any infection you/your child have worse.

What are the ingredients in AMGEVITA?

The active substance is adalimumab.

- Each 0.8 mL prefilled SureClick® autoinjector contains 40 mg of adalimumab (50 mg/mL)

The other ingredients are glacial acetic acid, polysorbate 80, sodium hydroxide, sucrose and water for injection.

AMGEVITA comes in the following dosage forms:

AMGEVITA is available in the presentations listed below. Your/your child's doctor will prescribe the type that is best for you/your child.

- 40 mg/0.8 mL (50 mg/mL) single-use prefilled autoinjector (SureClick®)
- 20 mg/0.4 mL (50 mg/mL) or 40 mg/0.8 mL (50 mg/mL) single-use prefilled syringe

Do not use AMGEVITA if you/your child:

- have an allergy to any of the ingredients in AMGEVITA (see **What are the ingredients in AMGEVITA?** section). The yellow cap on the AMGEVITA SureClick® autoinjector contains a needle cover that is composed of dry natural rubber, which is made from latex.
- have a serious infection such as tuberculosis, infections caused by bacteria or fungi, and bacterial infections that have spread throughout the body (sepsis).
- child have moderate to severe heart failure (NYHA class III/IV).

To help avoid effects and ensure proper use, talk to your/your child's healthcare professional before you/your child take AMGEVITA. Talk about any health conditions or problems you/your child may have, including if you/your child:

- have or have had any kind of infection including an infection that is in only one place in your body (such as an open cut or sore), or an infection that is in your whole body (such as the flu). Having an infection could put you/your child at risk for serious side effects from AMGEVITA. If you are unsure, ask your/your child's doctor.
- have a history of infections that keep coming back or other conditions that might increase your/your child's risk of infections, including fungal infections.
- have ever had tuberculosis, or if you/your child have been in close contact with someone who has had tuberculosis. If you/your child develop any of the symptoms of tuberculosis (a dry cough that doesn't go away, weight loss, fever, night sweats) call your/your child's doctor right away. Your/your child's doctor will need to examine you/your child for tuberculosis and perform a skin test.
- resided or traveled to areas where there is a greater risk for certain kinds of infections such as tuberculosis, histoplasmosis, coccidioidomycosis, blastomycosis, or parasitic infections. These infections are caused by a bacteria or a fungus that can affect the lungs or other parts of your/your child's body. If you/your child take AMGEVITA these may become active or more severe. If you/your child don't know if you have lived in or travelled to an area where these infections are common, ask your/your child's doctor.
- have ever had liver injury or hepatitis B virus infection or are a risk of developing this infection. Signs and symptoms include the following: yellowing of the skin or eyes (jaundice), feeling of sickness, tiredness, loss of appetite, joint pain, fever, dark brown-coloured urine, vomiting, and abdominal pain. If you/your child experience any of these signs and symptoms, contact your/your child's doctor immediately. These symptoms may occur several months after starting therapy with AMGEVITA.
- experience any numbness or tingling or have ever had a disease that affects your nervous system like multiple sclerosis or Guillain-Barré syndrome.
- have or have had heart failure.

- are scheduled to have major surgery or dental procedures.
- are scheduled to be vaccinated for anything. It is recommended that pediatric Crohn's disease patients, if possible, be brought up to date with all immunizations according to current guidelines before starting AMGEVITA.
- are taking other medicines for your rheumatoid arthritis, polyarticular juvenile idiopathic arthritis, psoriatic arthritis, ankylosing spondylitis, Crohn's disease, psoriasis, or other conditions. You/your child can take other medicines provided your doctor has prescribed them or has told you it is acceptable to take them while you are taking AMGEVITA. It is important that you tell your/your child's doctor about any other medicines you/your child are taking for other conditions (for example, high blood pressure medicine) before you/your child start taking AMGEVITA.
- are taking other medicines for you/your child's Crohn's disease or other conditions. You/your child can take other medicines provided the doctor has prescribed them or has told you it is acceptable that you/your child takes them while he/she is taking AMGEVITA. It is important that you tell the doctor about any other medicines you/your child is taking for other conditions before you/your child starts taking AMGEVITA.
- are taking any over-the-counter drugs, herbal medicines and vitamin and mineral supplements.
- are pregnant or could become pregnant.
- are breast-feeding or plan to breast-feed.
- are allergic to latex.

Other warnings you should know about:

Before starting, during and after treatment with AMGEVITA, you or your child should be checked for active or inactive tuberculosis infection with a tuberculin skin test.

If you/your child received AMGEVITA while pregnant, your/her baby may be at higher risk for getting an infection for up to approximately five months after the last dose of AMGEVITA received during pregnancy. It is important that your/her baby's doctors and other healthcare professionals know about your/her AMGEVITA use during pregnancy so they can decide when your/her baby should receive any vaccine.

Tell your healthcare professional about all the medications you take, including any drugs, vitamins, minerals, natural supplements, or alternative medicines.

The following may interact with AMGEVITA:

- other TNF-blockers such as Enbrel®, Remicade®, Cimzia®, or Simponi®
- abatacept (Orenica®)
- anakinra (Kineret®)

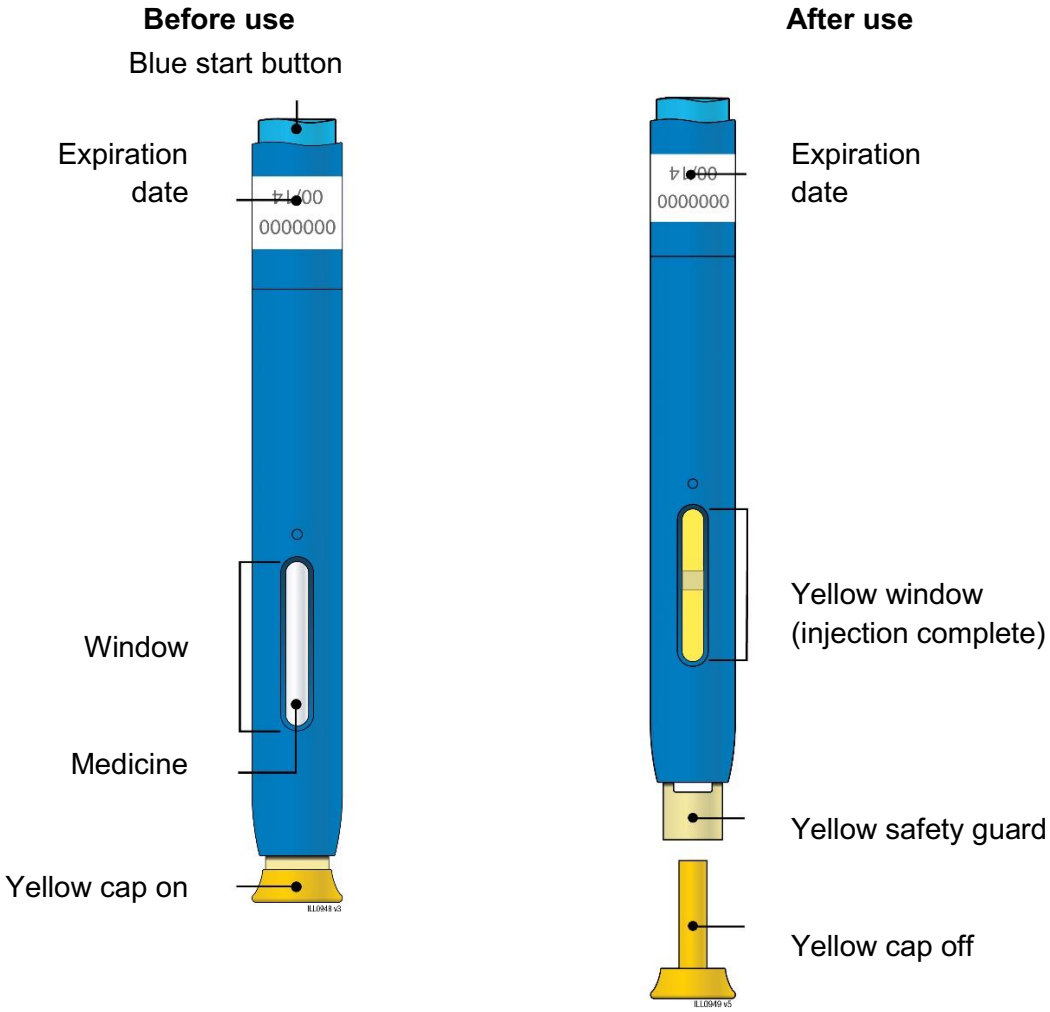
How to use AMGEVITA:

AMGEVITA is given as an injection under the skin (subcutaneous or SC).

AMGEVITA Single-use Prefilled SureClick® Autoinjector

The following instructions are for preparing and giving an injection of AMGEVITA using a single-use prefilled SureClick® autoinjector.

Guide to parts



Important: Needle is inside

Important:

Before you use an AMGEVITA SureClick® autoinjector, read this important information:

Storing your AMGEVITA SureClick® autoinjector

- Keep the AMGEVITA SureClick® autoinjector out of the reach of children.
- Keep the AMGEVITA SureClick® autoinjector in the original carton to protect from light or physical damage.
- The AMGEVITA SureClick® autoinjector should be kept in the refrigerator (2°C to 8°C).
- If needed, you may store the AMGEVITA SureClick® autoinjector at room temperature at 20°C to 25°C for up to 14 days. Throw away AMGEVITA that has been stored at room temperature after 14 days.
- **Do not** store the AMGEVITA SureClick® autoinjector in extreme heat or cold. For example, avoid storing in your vehicle's glove box or trunk.
- **Do not** freeze.

Using your AMGEVITA SureClick® autoinjector

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

- **Do not** use an AMGEVITA SureClick® autoinjector after the expiration date on the label.
- **Do not** shake the AMGEVITA SureClick® autoinjector.
- **Do not** remove the yellow cap from the AMGEVITA SureClick® autoinjector until you are ready to inject.
- **Do not** use the AMGEVITA SureClick® autoinjector if it has been frozen.
- **Do not** use an AMGEVITA SureClick® autoinjector if it has been dropped on a hard surface. Part of the AMGEVITA SureClick® autoinjector may be broken even if you cannot see the break. Use a new AMGEVITA SureClick® autoinjector.
- The yellow cap on the AMGEVITA SureClick® autoinjector contains a needle cover that is composed of dry natural rubber, which is made from latex. Tell your healthcare provider if you are allergic to latex.
- For more information or help call 1-866-502-6436.

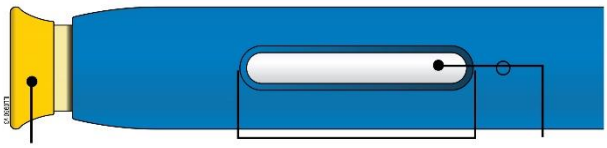
Step 1: Prepare

A. Remove one AMGEVITA SureClick® autoinjector from the package.

1. Carefully lift the autoinjector straight up out of the box.
2. Put the original package with any unused autoinjectors back in the refrigerator.
3. For a more comfortable injection, leave the autoinjector at room temperature for **15 to 30** minutes before injecting.

- **Do not** put the autoinjector back in the refrigerator once it has reached room temperature.
- **Do not** try to warm the 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 SureClick® autoinjector.



Yellow cap on Window Medicine

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

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

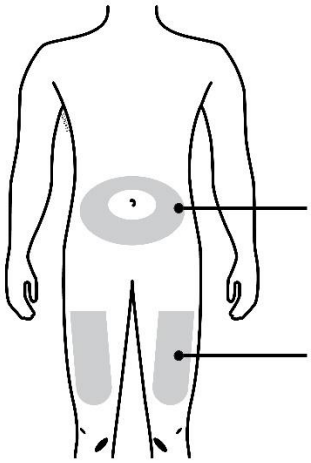
  In all cases, use a new autoinjector, and call 1-866-502-6436.

C. Gather all materials needed for your injection.

Wash your hands thoroughly with soap and water. On a clean, well-lit work surface, place the:

- New autoinjector
- Alcohol wipes
- Cotton ball or gauze pad
- Adhesive bandage
- Sharps disposal container

D. Prepare and clean your injection site.



You can use:

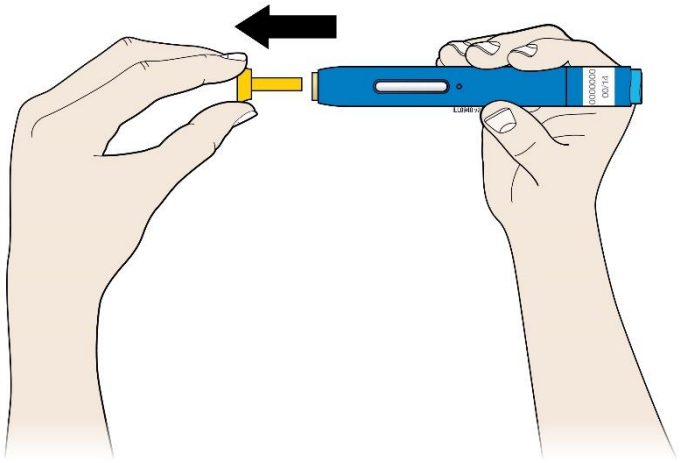
- Your thigh
- Stomach area (abdomen), except for a **5** centimetre (**2**-inch) area around your navel.

Clean the 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 straight off when you are ready to inject.

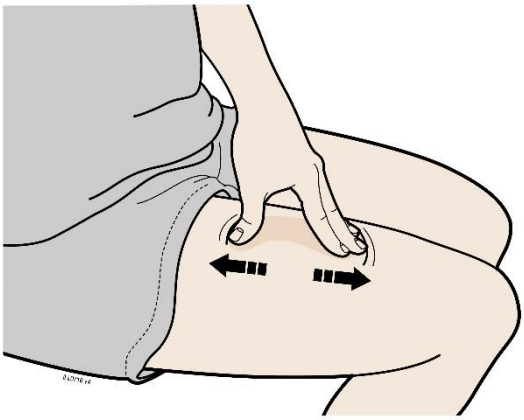


It is normal to see a drop of liquid at the end of the needle or yellow safety guard.

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

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

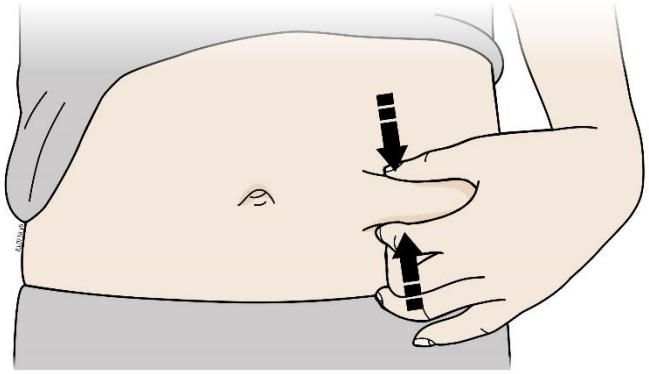
Stretch method



Stretch skin firmly by moving your thumb and fingers in opposite directions, creating an area about **5** centimetres (**2** inches) wide.

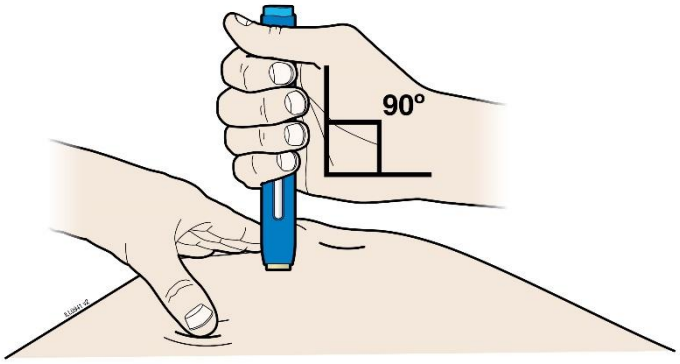
OR

Pinch method



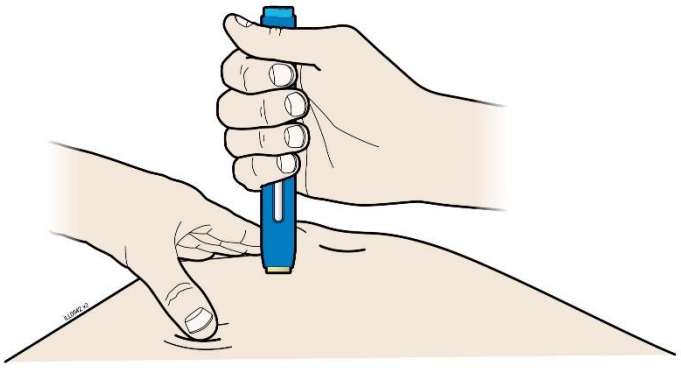
Step 3: Inject

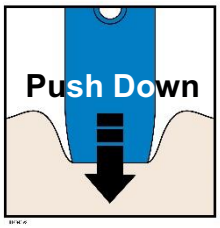
G. Hold the stretch or pinch. With the yellow cap off, **place** autoinjector on skin at 90 degrees.



Important: Do not touch the blue start button yet.

H. Firmly **push** the autoinjector onto skin until it stops moving.

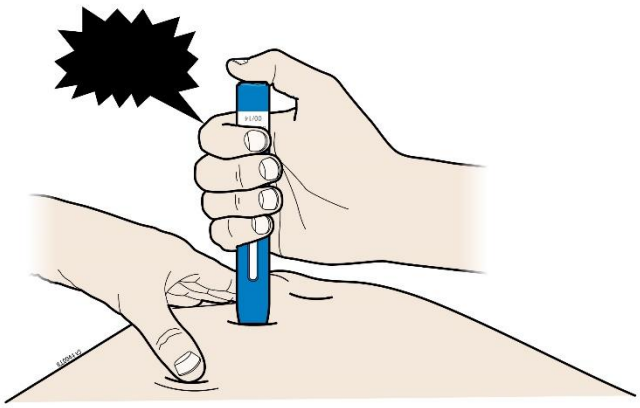




Important: You must push all the way down but **do not** touch blue start button until you are ready to inject.

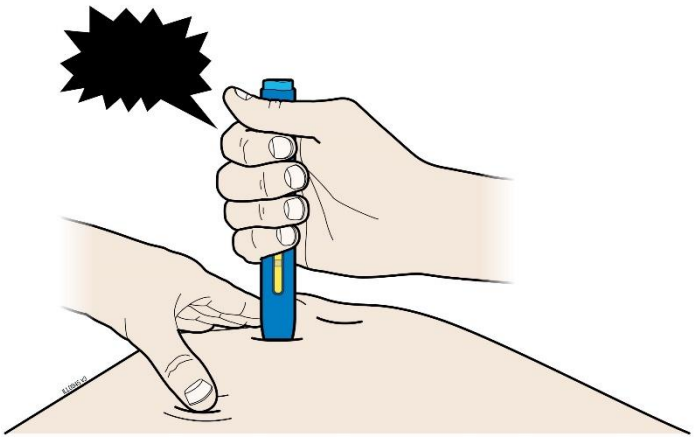
I. When you are ready to inject, **press** the blue start button.

"Click"

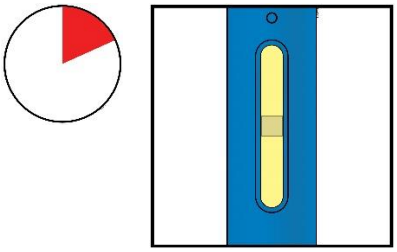


J. Keep **pushing** down on your skin. Your injection could take about 10 seconds.

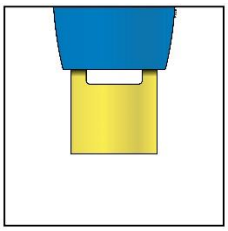
"Click"



~10s



Window turns yellow when injection is done

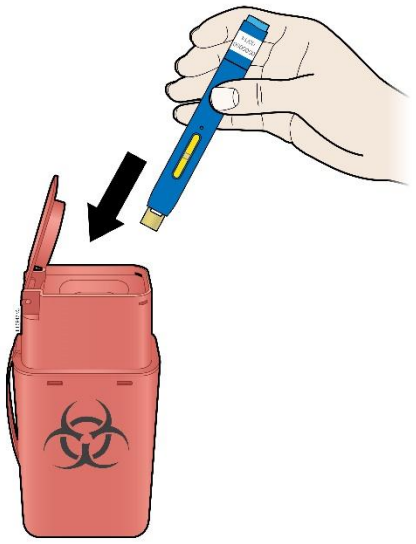


NOTE: After you remove autoinjector from your skin, the needle will be automatically covered.

Important: When you remove the 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 autoinjector and the yellow cap.



- Put the used SureClick® Autoinjector in a sharps disposal container right away after use. Do not throw away (dispose of) the SureClick® Autoinjector in your household trash.
- If you do not have a sharps disposal container, you may use a household container that is:
  - made of a heavy-duty plastic,
  - can be closed with a tight-fitting, puncture-resistant lid, without sharps being able to come out,
  - upright and stable during use,
  - leak-resistant, and
  - properly labeled to warn of hazardous waste inside the container.
- When your sharps disposal container is almost full, you will need to follow your community guidelines for the right way to dispose of your sharps disposal container. There may be provincial or local laws about how you should throw away used needles and syringes.
- **Important:** Always keep the autoinjector and the sharps disposal container out of the reach of children.
- **Do not** reuse the autoinjector.
- **Do not** recycle the autoinjector or sharps disposal container or throw them into household trash.

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 an adhesive bandage if needed.

Commonly asked questions

What will happen if I press the blue start button before I am ready to do the injection on my skin?

Even when you press the blue start button, the injection will only happen when the yellow safety guard is also pushed into the autoinjector.

Can I move the autoinjector around on my skin while I am choosing an injection site?

It is okay to move the autoinjector around on the injection site as long as you **do not** press the blue start button. However, if you press the blue start button and the yellow safety guard is pushed into the autoinjector, the injection will begin.

Can I release the blue start button after I start my injection?

You can release the blue start button, but continue to hold the autoinjector firmly against your skin during the injection.

Will the blue start button pop up after I release my thumb?

The blue start button may not pop up after you release your thumb if you held your thumb down during the injection. This is okay.

What do I do if I didn't hear a click after pushing the device down on my skin for 10 seconds?

If you didn't hear a click, you can confirm a complete injection by checking that the window has turned yellow.

Whom do I contact if I need help with the autoinjector or my injection?

If you have any questions about the autoinjector, its storage, or about your injection call 1-866-502-6436 for help.

Usual Dose:

Adults with Rheumatoid Arthritis, Psoriatic Arthritis or Ankylosing Spondylitis:

- The recommended dose is 40 mg administered every other week as a subcutaneous injection.

Patients, aged 2 years and older, with polyarticular juvenile idiopathic arthritis:

- Weighing 10 kg to less than 30 kg: The recommended dose of AMGEVITA is 20 mg every other week.
- Weighing 30 kg or more: The recommended dose of AMGEVITA is 40 mg every other week.

For patients who do not require a full 40 mg dose of AMGEVITA, a 20 mg pre-filled syringe is also available.

Adults with Crohn's Disease or Ulcerative Colitis:

- The recommended induction dose is 160 mg at Week 0 (dose can be administered as four injections in one day or as two injections per day for two consecutive days), followed by 80 mg at Week 2.
- The recommended maintenance dose regimen is 40 mg every other week beginning at Week 4.

Children, 13 to 17 years of age weighing ≥ 40 kg, with Crohn's disease:

- The recommended dose is 160 mg initially at Week 0 (given as four 40 mg injections in one day, or as two 40 mg injections per day for two consecutive days), followed by 80 mg at Week 2 (given as two 40 mg injections). At Week 4, your child will begin a maintenance dose of 20 mg every other week. Depending on your child's response, the doctor may increase the dose to 40 mg every other week (given as one 40 mg injection).

  For children who do not require a full 40 mg dose of AMGEVITA, a 20 mg pre-filled syringe is also available.

Adults with Hidradenitis Suppurativa:

- The recommended initial dose is 160 mg, followed by 80 mg two weeks later. The first dose of 160 mg can be administered as four injections in one day or as two injections per day for two consecutive days. The second dose of 80 mg is given as two 40 mg injections in one day.
- The recommended maintenance dose regimen is 40 mg every week beginning four weeks after the initial dose.

Adolescents, 12 to 17 years of age weighing ≥ 30 kg, with Hidradenitis Suppurativa:

- The recommended initial dose is 80 mg administered by subcutaneous injection, followed by 40 mg every other week starting one week later. Depending on your/your child's response, the doctor may increase the dose to 40 mg every week.

Adults with Psoriasis or Uveitis:

- The recommended dose is an initial dose of 80 mg, followed by 40 mg given every other week starting one week after the initial dose.

Children, from 2 years of age, with Uveitis:

- weighing less than 30 kg: the usual dose of AMGEVITA is 20 mg every other week with methotrexate. Your child's doctor may also prescribe an initial dose of 40 mg to be administered one week prior to the start of the usual dose if your child is older than 6 years of age.
- weighing 30 kg or more: the usual dose of AMGEVITA is 40 mg every other week with methotrexate. Your child's doctor may also prescribe an initial dose of 80 mg to be administered one week prior to the start of the usual dose.

For children who do not require a full 40 mg dose of AMGEVITA, a 20 mg pre-filled syringe is also available.

Overdose:

If you think you/your child have taken too much AMGEVITA, contact your/your child's healthcare professional, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

Missed Dose:

If you forget to give yourself or your child an injection, you should inject the missed dose of AMGEVITA as soon as you remember. Then administer the next dose as you would have on the originally scheduled date.

What are possible side effects from using AMGEVITA:

These are not all the possible side effects you may feel when taking AMGEVITA. If you experience any side effects not listed here, contact your healthcare professional. Please also see **Warnings and Precautions**.

Tell your/your child's doctor immediately if you/your child experience any of the following:

- severe rash, hives or other signs of allergic reaction
- swollen face, hands, feet
- trouble breathing, swallowing
- sudden weight gain (this is possibly indicative of new or worsening heart failure)
- bruising or bleeding very easily, looking very pale; this could mean a blood problem such as low red blood cells (anemia) or low platelets.

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

- signs of infection such as fever, malaise, wounds, dental problems, burning on urination
- feeling weak or tired
- coughing
- tingling
- numbness
- double vision
- arm or leg weakness
- arm or leg pain, swelling or redness
- bump or open sore that does not heal
- red scaly patches or raised bumps that are filled with pus; this could be new or worsening hidradenitis suppurativa, new or worsening psoriasis or a skin infection
- alopecia (loss of hair)
- changes in the colour of the skin
- changes in the colour of your urine (dark or red)
- worsening of the appearance of a scar

- night sweats
- weight loss
- pain in the abdomen or chest

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
VERY COMMON			
Injection site reaction		✓	
COMMON			
Cough and cold symptoms, including sore throat		✓	
Headache	✓		
Rash		✓	
Nausea		✓	
Pneumonia		✓	✓
Fever		✓	
Abdominal pain	✓		
UNCOMMON			
Tuberculosis		✓	✓
Other serious infections		✓	✓
Nerve disorders		✓	✓
Appendicitis		✓	✓
Blood clots: abdominal pain, chest pain, leg or arm pain with redness and swelling		✓	✓
Bladder infection (painful urination)		✓	✓
Hepatitis [jaundice (yellow skin, dark urine), abdominal pain, tiredness]		✓	✓

If you have troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

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 to 8°C). Do not freeze.

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

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

Keep out of reach and sight of children.

If you want more information about AMGEVITA:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website; the manufacturer's website www.amgen.ca, or by calling 1-866-502-6436.

This leaflet was prepared by Amgen Canada Inc.

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