**PATIENT INFORMATION LEAFLET**

**SCHEDULING STATUS:** **S4**

AMGEVITA® 20 mg solution for injection in pre-filled syringe.

AMGEVITA® 40 mg solution for injection in pre-filled syringe.

AMGEVITA® 40 mg solution for injection in pre-filled pen.

Adalimumab

Contains Sucrose

**Read all of this leaflet carefully before you start using AMGEVITA®**

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- AMGEVITA® has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

**What is in this leaflet**


1. What AMGEVITA® is and what it is used for
2. What you need to know before you use AMGEVITA®
3. How to use AMGEVITA®
4. Possible side effects
5. How to store AMGEVITA®
6. Contents of the pack and other information


## 1. What AMGEVITA® is and what it is used for

The active ingredient in AMGEVITA®, adalimumab, is a human monoclonal antibody. Monoclonal antibodies are proteins that attach to a specific target. The target of adalimumab is a protein called tumour necrosis factor (TNFα), which is involved in the immune (defence) system and is present at increased levels in the inflammatory diseases listed above. By attaching to TNFα, adalimumab decreases the process of inflammation in these diseases.

AMGEVITA® is intended for the treatment of the inflammatory diseases described below:

Adults:

- Rheumatoid arthritis is an inflammatory disease of the joints. AMGEVITA® is used to treat rheumatoid arthritis in adults.
- Psoriatic arthritis is an inflammation of the joints associated with psoriasis. AMGEVITA® is used to treat psoriatic arthritis in adults
- Plaque Psoriasis is a skin condition that causes red, flaky, crusty patches of skin covered with silvery scales. AMGEVITA® is used to treat plaque psoriasis in adults.
- AMGEVITA® is indicated for moderate to severe nail psoriasis in adult patients who are candidates for systemic therapy
- Axial spondyloarthritis including ankylosing spondylitis is the inflammatory diseases of the spine. AMGEVITA® is used to treat axial spondyloarthritis in adults
- Ankylosing spondylitis is the inflammatory diseases of the spine. AMGEVITA® is used to treat ankylosing spondylitis in adults
- Crohn's disease is an inflammatory disease of the digestive tract. AMGEVITA® is used to treat Crohn's disease in adults.
- Ulcerative colitis is an inflammatory disease of the bowel. AMGEVITA® is used to treat ulcerative colitis in adults.
- Hidradenitis suppurativa (sometimes called acne inversa) is a chronic and often painful inflammatory skin disease. Symptoms may include tender nodules (lumps) and abscesses (boils) that may leak pus. It most commonly affects specific areas of the skin, such as under the breasts, the armpits, inner thighs, groin and buttocks. Scarring may also occur in affected areas. AMGEVITA® is used to treat hidradenitis suppurativa in adults.
- Uveitis is an inflammatory disease affecting certain parts of the eye. AMGEVITA® is used to treat adult with non-infections uveitis.
- Polyarticular juvenile idiopathic arthritis is an inflammatory disease of the joints that usually first appears in childhood. AMGEVITA® is used to treat polyarticular juvenile idiopathic arthritis in patients from 2 years of age.
- Paediatric Crohn's disease is an inflammatory disease of the digestive tract. AMGEVITA® is

used to treats Crohn's disease in children and adolescents from 6 years of age and older.

- Paediatric plaque psoriasis is a skin conditions that causes red flaky, crusty patches of the skin covered with silvery scales. AMGEVITA® is used to treat plaque psoriasis in children and adolescents from 4 years of age.
- Paediatric uveitis: Non-infections uveitis is an inflammatory disease affecting certain parts of the eye. AMGEVITA® is used to treat children with chronic non-infections uveitis from 2 years of age with inflammation affecting the front of the eye.

## 2. What you need to know before you use AMGEVITA®

**Do not use AMGEVITA®:**

- if you are hypersensitive (allergic) to adalimumab or any of the other ingredients of AMGEVITA® (listed in section 6).
- if you have a severe infection, including active tuberculosis (see "Warnings and precautions"). It is important that you tell your doctor if you have symptoms of infections, e.g. fever, wounds, feeling tired, dental problems.
- if you have moderate or severe heart failure. It is important to tell your doctor if you have had or have a serious heart condition (see "Warnings and precautions").
- If you are to receive live vaccines, they should not be given while receiving AMGEVITA®. Please check with your doctor before you receive any vaccines.

**Warnings and precautions**

Talk to your doctor or pharmacist before using AMGEVITA®:

- If you experience allergic reactions with symptoms such as chest tightness, wheezing, dizziness, difficulty to breach, swelling of the face, hands, feet, throat or rash do not inject more AMGEVITA® and contact your doctor immediately.
- If you have an infection, including long-term or localised infection (for example, leg ulcer) consult your doctor before starting AMGEVITA®. If you are unsure, please contact your doctor.
- You might get infections more easily while you are receiving AMGEVITA® treatment. including serious infections, tuberculosis, opportunistic infections and sepsis that may be life-

threatening. It is important to tell your doctor if you get symptoms such as fever, wounds, feeling tired or dental problems.

- As cases of tuberculosis have been reported in patients treated with adalimumab, your doctor will check you for signs and symptoms of tuberculosis before starting AMGEVITA®. This will include a thorough medical evaluation including your medical history and appropriate screening tests (for example chest x-ray and a tuberculin test). The conduct and results of these tests should be recorded on your Patient Alert Card. It is very important that you tell your doctor if you have ever had tuberculosis, or if you have been in close contact with someone who has had tuberculosis. Tuberculosis can develop during therapy even if you have received preventative treatment for tuberculosis. If symptoms of tuberculosis (persistent cough, weight loss, listlessness, mild fever), or any other infection appear during or after therapy, tell your doctor immediately.
- Advise your doctor if you have a history of recurrent infections or other conditions that increase the risk of infections.
- Advise your doctor if you are a carrier of the hepatitis B virus (HBV), if you have active HBV or if you think you might be at risk of contracting HBV. Your doctor should test you for HBV. AMGEVITA® can cause reactivation of HBV in people who carry this virus. In some rare cases, especially if you are taking other medicines that suppress the immune system, reactivation of HBV can be life-threatening.
- If you are about to undergo surgery or dental procedures please inform your doctor that you are taking AMGEVITA®.
- If you have multiple sclerosis, your doctor will decide if you should receive AMGEVITA®.
- Some vaccines should not be given while receiving AMGEVITA®. Please check with your doctor before you receive any vaccines.
- If you have mild heart failure and you are being treated with AMGEVITA®, your heart failure status must be closely monitored by your doctor. It is important to tell your doctor if you have had or have a serious heart condition. If you develop new or worsening symptoms of heart failure (e.g. shortness of breath, or swelling of your feet), you must contact your doctor immediately.

- In some patients the body may fail to produce enough of the blood cells that help your body fight infections or help you to stop bleeding. If you develop fever that does not go away, bruise or bleed very easily or look very pale, call your doctor right away. Your doctor may decide to stop treatment.
- There have been ~~very rare~~ cases of certain kinds of cancer in patients taking adalimumab or other TNF blockers. 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 (lymphoma) or the cancer of the white blood cells (leukaemia). If you take AMGEVITA® your risk may increase. In addition, very rare cases of non-melanoma skin cancer have been observed in patients taking adalimumab.
- Cancers, other than lymphoma, have been reported in patients with a specific type of lung disease called Chronic Obstructive Pulmonary Disease (COPD) treated with another TNF blocker. If you have COPD, or are a heavy smoker, you should discuss with your doctor whether treatment with a TNF blocker is appropriate for you.
- Caution should be used when treating the elderly because there is a higher incidence of infections in the elderly population.

**Children and adolescents**

- Vaccinations: if possible children should be up to date with all vaccinations before using AMGEVITA®.

**Other medicines and AMGEVITA®**

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

AMGEVITA® can be taken together with methotrexate or certain disease-modifying anti-rheumatic agents (sulfasalazine, hydroxychloroquine, leflunomide and injectable gold preparations), steroids or pain medications including non-steroidal anti- inflammatory drugs (NSAIDs).

Please tell your doctor or pharmacist if you are taking or have taken any other medicines including medicines obtained without a prescription.

You should not take AMGEVITA® with medicines containing the active substances, anakinra or abatacept . If you have questions, please ask your doctor.

**AMGEVITA® with food and drink**

Since AMGEVITA® is given subcutaneously, food and drink should not affect AMGEVITA®.

**Pregnancy and breastfeeding**

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

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. AMGEVITA® should only be used during a pregnancy if needed. According to a pregnancy study, there was no higher risk of birth defects when the mother had received adalimumab during pregnancy compared with mothers with the same disease who did not receive adalimumab.

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.

**Driving and using machines**

AMGEVITA® should not affect your ability to drive or use machinery.

**AMGEVITA® contains Sucrose**

AMGEVITA® contains sucrose which may have an effect on the control of your blood sugar if you have diabetes mellitus. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before using AMGEVITA®.

## 3. How to use AMGEVITA®

Do not share medicines prescribed for you with any other person.

Always use AMGEVITA® exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are not sure. Your doctor will tell you how long your treatment with AMGEVITA® will last.

AMGEVITA® is injected under the skin (subcutaneous use).

Adults

The usual dose for adults with rheumatoid arthritis, psoriatic arthritis and axial spondyloarthritis including ankylosing spondylitis is 40 mg of AMGEVITA® given every other week as a single dose.

The recommended AMGEVITA® dose regimen for adult patients with Crohn's disease 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), 80 mg at week 2, and followed 2 weeks later by a maintenance dose of 40 mg every other week via subcutaneous injection.

The recommended AMGEVITA® dose regimen for adult patients with ulcerative colitis 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) and 80 mg at Week 2, and thereafter 40 mg every other week. Depending on your response, your doctor may increase the dose to 40 mg every week.

The usual dose for adults with psoriasis is an initial does of 80 mg, followed by 40 mg given every other week starting one week after the initial dose. Depending on your response, your doctor may increase the dose to 40 mg every week.

Adults with Hidradenitis Suppurativa

The usual dose regimen for hidradenitis suppurativa is an initial does of 160 mg (dose can be administered as four injections in one day or as two injections per day for two consecutive days), followed by 80 mg (as two injections on the same day) two weeks later. After two further weeks,

continue with a dose of 40 mg every week. It is recommended that you use an antiseptic wash daily on the affected areas.

Uveitis

The recommended dose of AMGEVITA® for adult patients with uveitis is an initial dose of 80 mg, followed by 40 mg given every other week starting one week after the initial dose.

AMGEVITA® can be used alone or in combination with corticosteroids.

Paediatrics

| Polyarticular juvenile idiopathic arthritis | | |
|---|---|---|
| Age or body weight | How much and how often to take? | Notes |
| Children, adolescents and adults from 2 years of age weighing 30 kg or more | 40 mg every other week | |
| Children and adolescents from 2 years of age weighing 10 kg to less than 30 kg | 20 mg every other week | |
| Plaque psoriasis | | |
| Age or body weight | How much and how often to take? | Notes |
| Children and adolescents from 4 to 17 years of age weighing 30 kg or more | First dose of 40 mg, followed by 40 mg one week later.<br><br>Thereafter, the usual dose is 40 mg every other week. | |
| Children and adolescents from 4 to 17 years of age weighing 15 kg to less than 30 kg | First dose of 20 mg, followed by 20 mg one week later.<br><br>Thereafter, the usual dose is 20 mg every other week. | |
| Paediatric Crohn's disease | | |

| Age or body weight | How much and how often to take? | Notes |
|---|---|---|
| Children and adolescents from 6 to 17 years of age weighing 40 kg or more | First dose of 160 mg, followed by 80 mg two weeks later.<br><br>Thereafter, the usual dose is 40 mg every other week | Your child's doctor may increase the dose frequency to 40 mg every week. |
| Children and adolescents from 6 to 17 years of age weighing less than 40 kg | First dose of 80 mg, followed by 40 mg two weeks later.<br><br>Thereafter, the usual dose is 20 mg every other week | Your child's doctor may increase the dose frequency to 20 mg every week. |

Paediatric uveitis

The recommended dose of AMGEVITA® for paediatric patients 2 years of age and older with chronic non-infectious uveitis is based on body weight (table 4).

AMGEVITA® is administered via subcutaneous injection. AMGEVITA® may be available in other strengths and/or presentations.

AMGEVITA® may be used in combination with methotrexate or other non-biologic immunomodulatory agents based on clinical judgment.

**Table 1**

| Patients (2 years of age and older) | Dose |
|---|---|
| < 30 kg | 20 mg every other week |
| ≥ 30 kg | 40 mg every other week |

You should continue to inject AMGEVITA® for as long as instructed by your doctor.

In rheumatoid arthritis and juvenile idiopathic arthritis, methotrexate is continued while using AMGEVITA®. If your doctor determines that methotrexate is inappropriate, AMGEVITA® can be given alone.

If you have rheumatoid arthritis and you do not receive methotrexate with your AMGEVITA® therapy, your doctor may decide to give 40 mg of AMGEVITA® every week.

**Method and route of administration**

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

**If you use more AMGEVITA® than you should**

If you accidentally inject AMGEVITA® more frequently than told to by your doctor or pharmacist, call your doctor or pharmacist and tell him/her that you have taken more.
Always take the outer carton of this medicine with you, even if it is empty.

**If you forget to use AMGEVITA®**

If you forget to give yourself an injection, you should inject the next dose of AMGEVITA® as soon as you remember. Then take your next dose as you would have on your originally scheduled day, had you not forgotten a dose. If you have any further questions on the use of the product, ask your doctor or pharmacist.

**If you stop using AMGEVITA®**

The decision to stop using AMGEVITA® should be discussed with your doctor. Your symptoms may return upon discontinuation.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

## 4. Possible side effects

AMGEVITA® can have side effects**:**
Not all side effects reported for AMGEVITA® are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking AMGEVITA®, please consult your health care provider for advice.

If any of the following happens, tell your healthcare professional immediately or go to the casualty department at your nearest hospital:

- severe rash, hives or other signs of allergic reaction;
- swollen face, eyelids, lips, tongue, throat, hands, feet;
- trouble breathing, swallowing;
- shortness of breath with exertion or upon lying down or swelling of the feet.
- signs and symptoms suggestive of blood disorders such as persistent fever, bruising, bleeding, paleness.
- These are very serious side effect. If you have them, you may have had a serious allergic to AMGEVITA®. You may need urgent medical attention or hospitalisation.

Tell your doctor as soon as possible if you 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;
- a bump or open sore that doesn't heal;

The symptoms described above can be signs of the below listed side effects, which have been observed with adalimumab.

Tell your doctor if you notice any of the following:

Frequent:

- injection site reactions (including pain, swelling, redness or itching);
- respiratory tract infections including lower and upper respiratory tract infections, pneumonia, inflammation of the mucous membranes of any sinus (sinusitis), inflammation of the mucous

membrane and underlying parts of the pharynx (pharyngitis, nasopharyngitis) and pneumonia herpes viral;

- anaemia, low white blood cell counts;
- headache;
- abdominal pain, nausea and vomiting;
- urinary tract infection, cold blisters, shingles, serious blood infections (such as Sepsis[blood poisoning]), fungal infections, ear infection, tooth infection, skin infection, wound infections;
- dizziness, headache;
- cough, sore throat, nausea, diarrhoea, abdominal pain, elevated liver enzymes;
- rash, itching, hair loss;
- fatigue
- allergic reactions
- mood alteration (including depression), anxiety, insomnia;
- asthma, shortness of breath, cough;
- vertigo;
- dehydration;
- joint infection;
- visual impairment, conjunctivitis (inflammation of the membrane that lines the eyelid), blepharitis (inflammation of the eye lids), eye swelling

Less frequent

- opportunistic infections and tuberculosis, eye infections, bacterial infections;
- skin wart;
- nerve disorders (such as multiple sclerosis, eye nerve inflammation), taste disturbances;
- double vision;
- confusion;
- sensation of heart beating rapidly, high blood pressure;
- abdominal symptoms (such as vomiting, indigestion, constipation), mouth ulcers, mouth disorder, toothache;
- skin disorders (such as eczema or infections), skin ulcer, itchy rash, slow wound healing;

- bursitis, muscle weakness;
- urinary disturbances (such as blood in the urine, increased urinary frequency at night);
- inflammation;
- abnormal lab results;
- Erectile dysfunction
- dizziness, tinnitus (buzzing in the ear);
- night sweats;
- neuropathy (an abnormal and usually degenerative state of the nervous system or nerves);
- systemic lupus erythematous (an inflammatory connective tissue disease of unknown cause that is characterised especially by fever, skin rash, and arthritis)

Other side effects that have been observed in patients taking adalimumab:

Tuberculosis and other opportunistic infections (infections that occur when resistance to disease is lowered), lung disease, baldness, a skin disease characterised by papular or vesicular lesions and reddening or discolouration of the skin often in concentric zones around the lesions, infection of diverticulum of the colon that is marked by abdominal pain or tenderness often accompanied by fever, chills and cramping, obstruction of blood vessel by blood clot that is marked by laboured breathing, sharp chest pain that is worse with cough or deep breaths due to accumulation of fluid between the layers of tissue that line the lungs and chest cavity, scarring of the lung tissue marked by difficulty in breathing, fainting, rapid heart rate, cyanosis, shock, and sometimes death, sarcoidosis (an inflammatory disease that starts as tiny, grain-like lumps called granulomas which most often appear in your lungs or lymph nodes).

The following side effects with unknown frequency have been observed in patients taking adalimumab:

- marked cell carcinoma (a type of skin cancer)
- pyrexia (fever)

If any side effects get serious, if you have any unusual effects or if you notice any side effects not listed in this leaflet, please tell your healthcare provider.

**Reporting of side effects**

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reaction Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8.

By reporting side effects, you can help provide more information on the safety of AMGEVITA®.

Alternatively, you can report side effects to:

Amgen South Africa (Pty) Ltd.

Tel: +27 (0)11 100 5300

Email: safety-south-africa@amgen.com

## 5. How to store AMGEVITA®

Store all medicines out of reach of children.

Do not use AMGEVITA® after the expiry date stated on the label/blister/ carton after EXP (the expiry date refers to the last day of that month).

Store in a refrigerator (2 – 8 ˚C). Do not freeze.

Keep the pre-filled pen/syringe in the outer carton.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

## 6. Contents of the pack and other information

**What AMGEVITA® contains**

- The active substance is adalimumab. Each pre-filled syringe contains 20 mg of adalimumab in 0.4 ml of solution or 40 mg of adalimumab in 0.8 ml of solution.
- The other ingredients are glacial acetic acid, sucrose, polysorbate 80, sodium hydroxide and water for injection.

**What AMGEVITA® looks like and contents of the pack**

Clear colourless glass syringe containing a clear and colourless to slightly yellow solution.

**AMGEVITA® 20 mg** solution for injection in single-use pre-filled syringe (type I glass) with a plunger stopper (grey bromobutyl rubber) steel and a needle with a needle shield (thermoplastic elastomer).

Pack size of one pre-filled syringe, placed in an outer carton.

**AMGEVITA® 40 mg** solution for injection in single-use pre-filled syringe (type I glass) with a plunger stopper (grey bromobutyl rubber) steel and a needle with a needle shield (thermoplastic elastomer).

Pack sizes of one and two pre-filled syringes, placed in an outer carton.

Not all pack sizes may be marketed.

**AMGEVITA® 40 mg** solution for injection in single-use pre-filled pen**.** The pre-filled pen is a single use, disposable, handheld, mechanical (spring-based) injection device which consists of a pre-filled syringe contained within two subassemblies:

- The front subassembly (blue) is designed to hold the pre-filled syringe with staked needle and non-rigid needle shield.
- The rear subassembly (blue) contains a plunger rod (blue) and spring that delivery.

Pack sizes of one and two pre-filled pens, placed in an outer carton.

Not all pack sizes may be marketed.

**Holder of Certificate of Registration**

Amgen South Africa (Pty) Ltd.

Building D, Ballyoaks Office Park,

35 Ballyclare Drive,

Bryanston Ext. 7, 2021,

South Africa

**This leaflet was last revised in**

20 October 2022

**Registration number**

Amgevita 20 mg: 51/30.1/0677

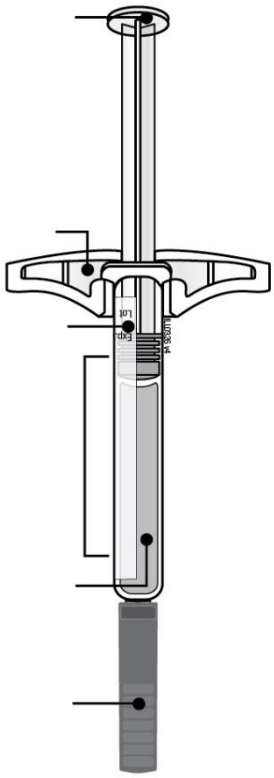
Amgevita 40 mg PFS and PFP: 51/30.1/0678

**Instructions for Use:**

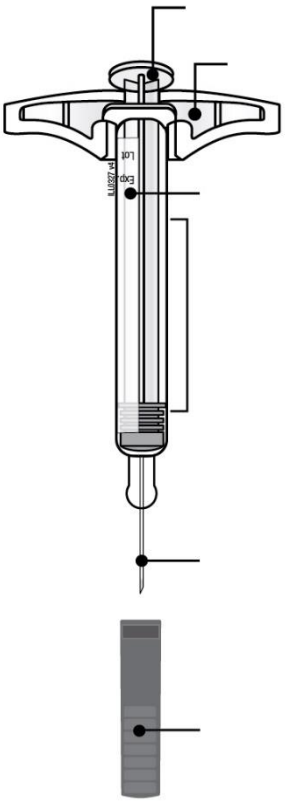
AMGEVITA® single use pre-filled syringe

**Guide to parts**

**Before use**




**After use**




**Important:** Needle is inside

**Important**

**Before you use an AMGEVITA® pre-filled syringe, read this important information:**

**Storing your AMGEVITA® pre-filled syringes**

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

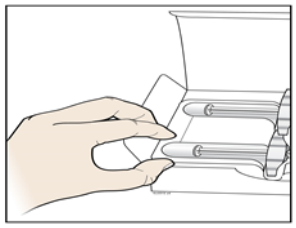
**Using your AMGEVITA® pre-filled syringe:**

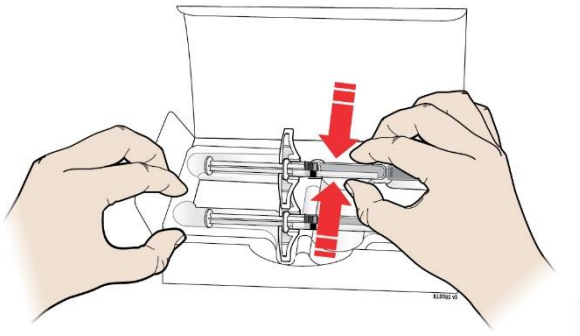
- It is important that you do not try to give the injection unless you or your caregiver has received training.
- **Do not** use an AMGEVITA® pre-filled syringe after the expiration date on the label.
- **Do not** shake the AMGEVITA® pre-filled syringe.
- **Do not** remove the needle cap from the AMGEVITA® pre-filled syringe until you are ready to inject.
- **Do not** use the AMGEVITA® pre-filled syringe if it has been frozen.
- **Do not** use an AMGEVITA® pre-filled syringe if it has been dropped on a hard surface. Part of the AMGEVITA® pre-filled syringe may be broken even if you cannot see the break. Use a new AMGEVITA® pre-filled syringe.

**Step 1: Prepare**

**A.** Remove the number of AMGEVITA® pre-filled syringes you need from the package.

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





**Grab Here**

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

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

For safety reasons:

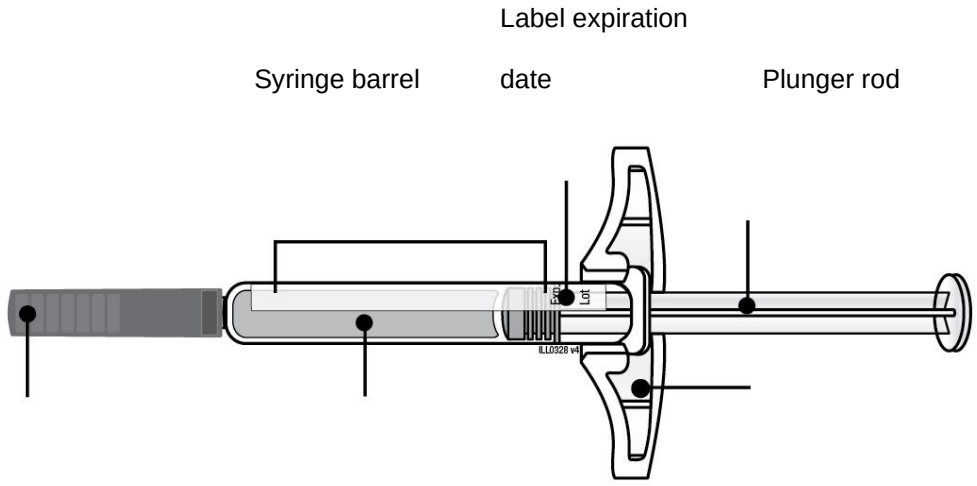
- **Do not** grasp the plunger rod.
- **Do not** grasp the needle cap.
- **Do not** remove the needle cap until you are ready to inject.
- **Do not** remove the finger flange. This is part of the syringe.

For a more comfortable injection, leave the 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 pre-filled syringe by the syringe barrel.

**B.** Inspect the AMGEVITA® pre-filled 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 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.

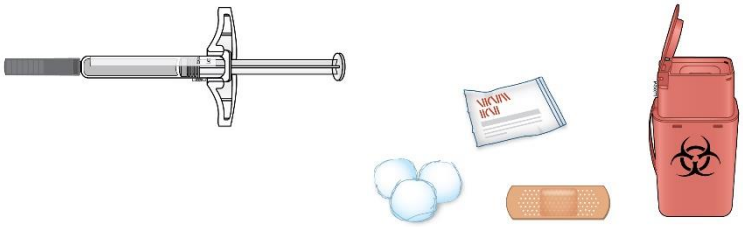
In all cases, use a new syringe.

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

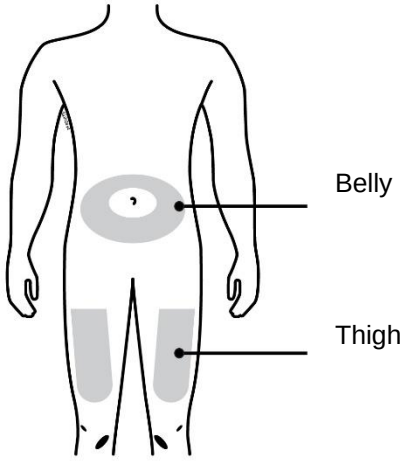
Wash your hands thoroughly with soap and water.

On a clean, well-lit work surface, place the:

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



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




**You can use:**

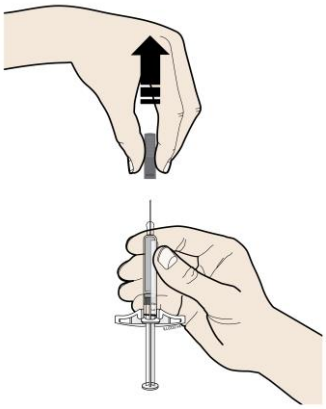
- Your thigh
- Belly, except for a 2 inch (5 centimetres) area around your belly button

Clean your 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.

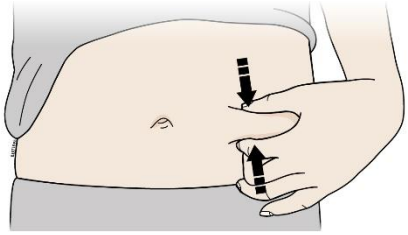


It is normal to see a drop of liquid at the end of the needle.

- **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.

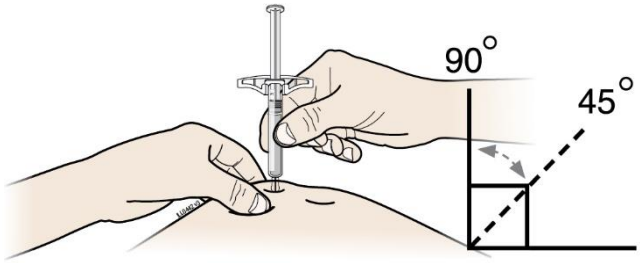


Pinch the skin firmly between your thumb and fingers, creating an area about 2 inches (5 centimetres) wide.

**Important:** Keep the skin pinched while injecting.

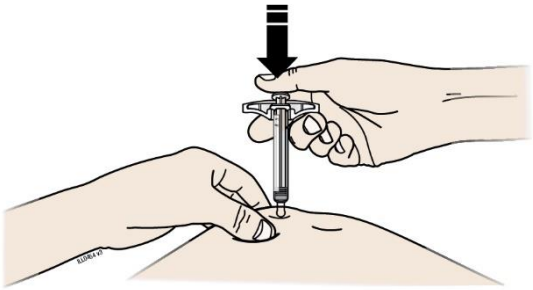
**Step 3: Inject**

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

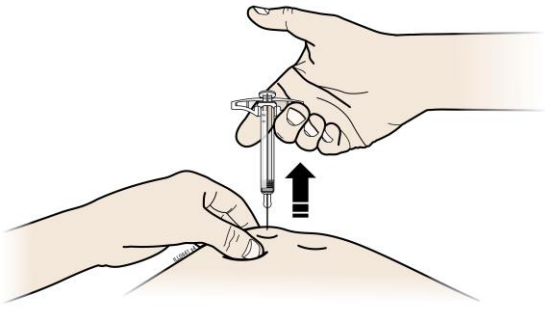



**Do not** place your finger on the plunger rod while inserting the needle.

**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 of your skin.



**Step 4: Finish**

**J.** Discard the used syringe and the needle cap.



- **Do not** reuse the used syringe.
- **Do not** use any medicine that is left in the used syringe.
- Put the used AMGEVITA® syringe in a sharps disposal container immediately after use. **Do not** throw away (dispose of) the syringe in your household waste.
- Talk with your doctor or pharmacist about proper disposal. There may be local guidelines for disposal.
- **Do not** reuse the syringe.
- **Do not** recycle the syringe or sharps disposal container or throw them into the household waste.

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

**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 a plaster if needed.

**Instructions for Use:**

AMGEVITA® single use SureClick pre-filled pen

**Guide to parts**

**Before use**

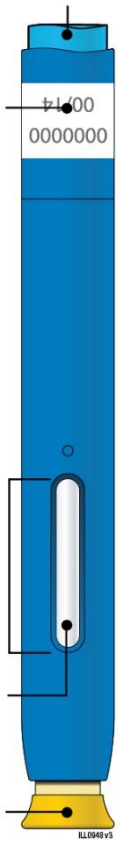
Blue start button

Expiration date

Window

Medicine

Yellow cap on



**After use**

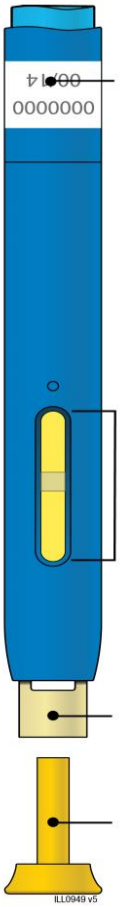
Expiration date

Yellow window

(injection complete)

Yellow safety guard

Yellow cap off



**Important:** Needle is inside

**Important**

**Before you use an AMGEVITA® pre-filled pen, read this important information:**

**Storing your AMGEVITA® pre-filled pens**

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

**Using your AMGEVITA® pre-filled pen**

- It is important that you do not try to give the injection unless you or your caregiver has received training.
- **Do not** use an AMGEVITA® pre-filled pen after the expiration date on the label.
- **Do not** shake the AMGEVITA® pre-filled pen.
- **Do not** remove the yellow cap from the AMGEVITA® pre-filled pen until you are ready to inject.
- **Do not** use the AMGEVITA® pre-filled pen if it has been frozen.
- **Do not** use an AMGEVITA® pre-filled pen if it has been dropped on a hard surface. Part of the AMGEVITA® pre-filled pen may be broken even if you cannot see the break. Use a new AMGEVITA® pre-filled pen.

**Step 1: Prepare**

**A.** Remove one AMGEVITA® pre-filled pen from the package.

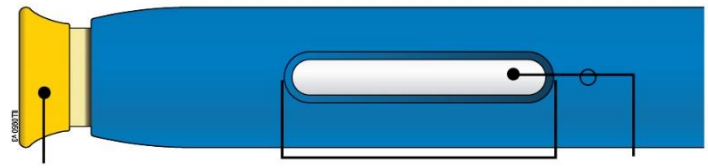
Carefully lift the pre-filled pen straight up out of the box.

Put the original package with any unused pre-filled pens back in the refrigerator.

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

- **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.
- **Do not** shake the pre-filled pen.
- **Do not** remove the yellow cap from the pre-filled pen yet.

**B.** Inspect the AMGEVITA® pre-filled pen.



Yellow cap on Window Medicine

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

- **Do not** use the pre-filled pen if:
  - The medicine is cloudy or discoloured, or contains flakes or particles.
  - Any part appears cracked or broken.
  - The pre-filled pen 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 pre-filled pen.

**C.** Gather all materials needed for your injection.

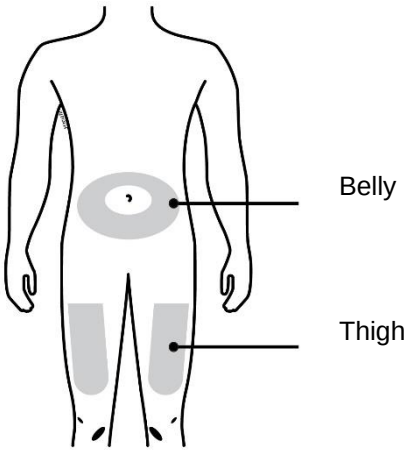
Wash your hands thoroughly with soap and water.

On a clean, well-lit work surface, place the:

- New pre-filled pen
- Alcohol wipes
- Cotton ball or gauze pad
- Plaster
- Sharps disposal container



**D.** Prepare and clean your injection site.




**You can use:**

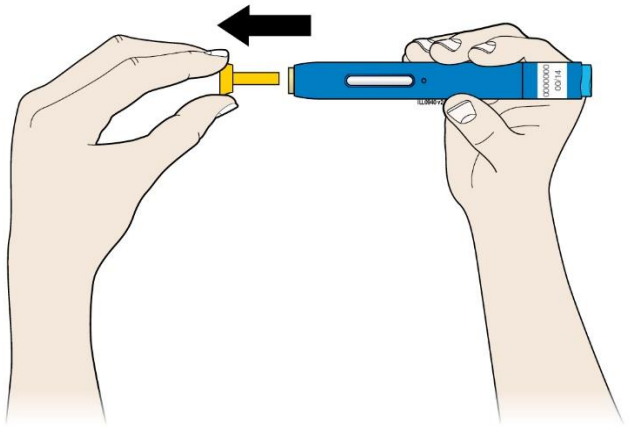
- Your thigh
- Belly, except for a 2-inch (5 centimetre) area right around your belly button

Clean your 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.

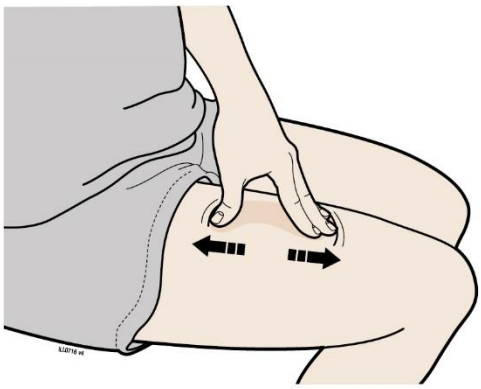


It is normal to see a drop of liquid at the end of the needle or yellow safety guard.

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

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

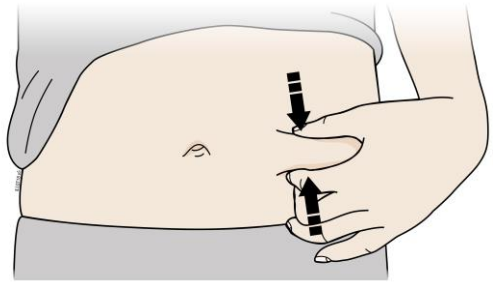
**Stretch method**



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

**OR**

**Pinch method**

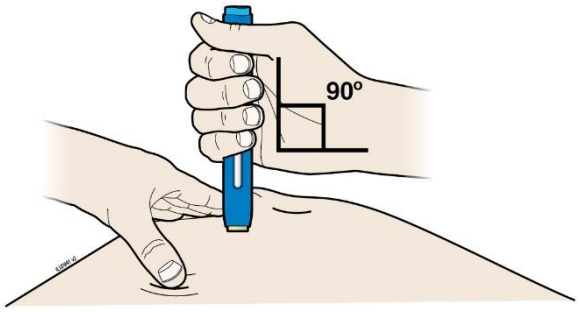


Pinch the skin firmly between your thumb and fingers, creating an area about **2** inches (**5** centimetres) wide.

**Important:** Keep the skin stretched or pinched while injecting.

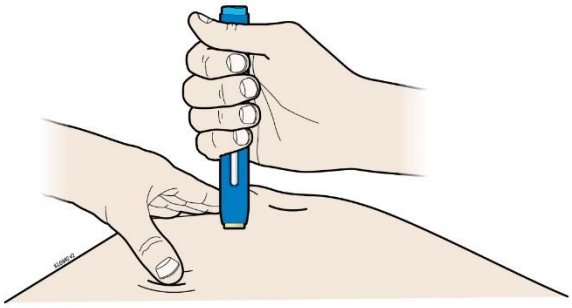
**Step 3: Inject**

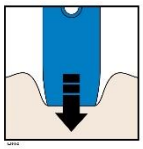
**G.** Hold the stretch or pinch. With the yellow cap off, **place** the pre-filled pen on your skin at 90 degrees.




**Important:** Do not touch the blue start button yet.

**H.** Firmly **push** the pre-filled pen down onto the skin until it stops moving.

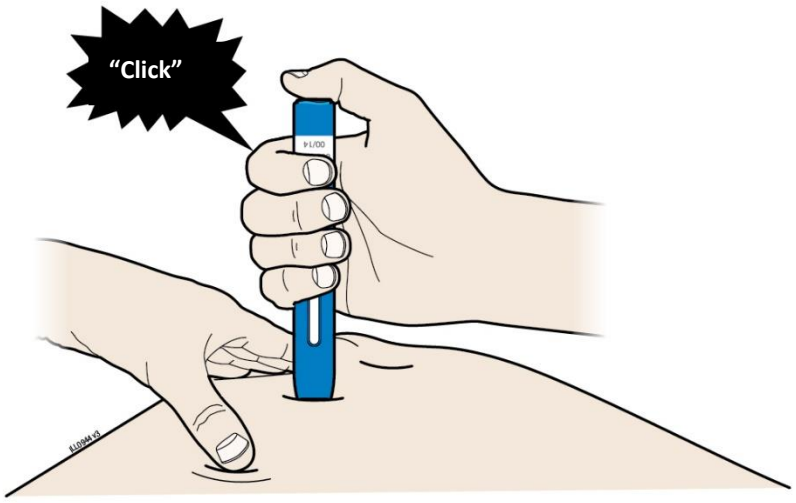




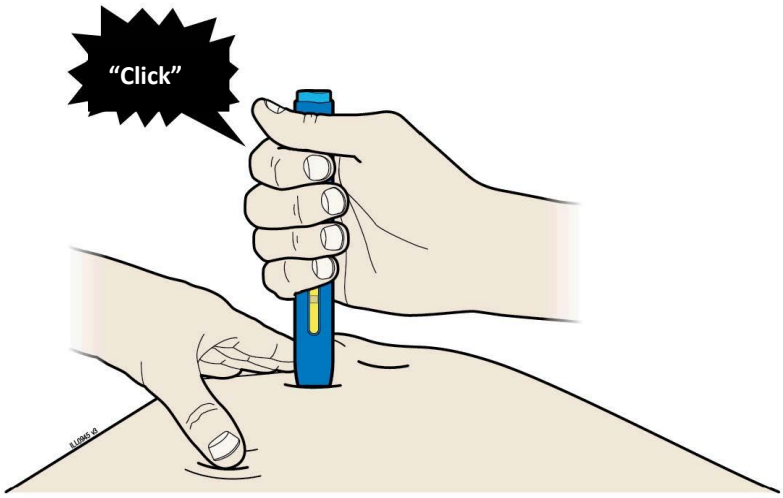
**Push down**

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

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

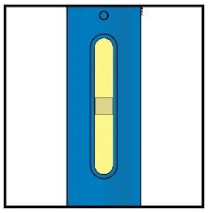


**J.** Keep **pushing** down on your skin. Your injection could take about 10 seconds.



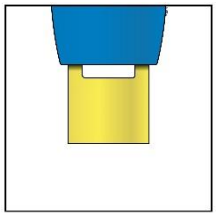

**~10s**





The window turns yellow

When the injection is done

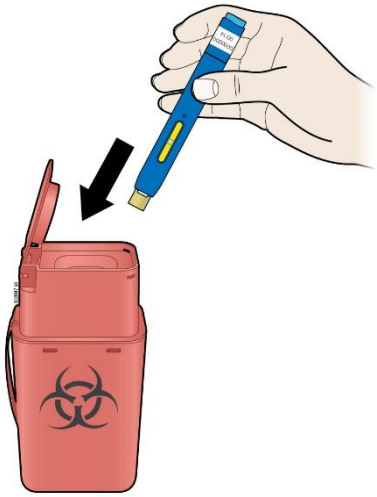


**Note:** After you remove the pre-filled pen from your skin, the needle will be automatically covered.

**Important:** When you remove the pre-filled 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.

**Step 4: Finish**

**K.** Discard the used pre-filled pen and the yellow cap.



- Put the used pre-filled pen in a sharps disposal container immediately after use. **Do not** throw away (dispose of) the pre-filled pen in your household waste.
- Talk with your doctor or pharmacist about proper disposal. There may be local guidelines for disposal.
- **Do not** reuse the pre-filled pen.
- **Do not** recycle the pre-filled pen or sharps disposal container or throw them into the household waste.

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

**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 a plaster if needed.