# AMGEVITA®
# pre-filled syringe
# pre-filled pen

*Adalimumab (ada-lim-u-mab)*

**Consumer Medicine Information (CMI)**

## What is in this CMI

This leaflet answers some common questions about AMGEVITA.

It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you using this medicine against the benefits they expect it will have for you.

**Speak to your doctor or pharmacist if you have any concerns about taking AMGEVITA.**

**Read this leaflet carefully before you use AMGEVITA and keep this leaflet with your medicine.**

You may need to read it again.

## What AMGEVITA is used for

AMGEVITA is a medicine used to treat the following inflammatory conditions:

- Rheumatoid arthritis (RA)
- Polyarticular juvenile idiopathic arthritis **(**polyarticular JIA)
- Enthesitis-related arthritis (ERA)
- Psoriasis (Ps)
- Psoriatic arthritis (PsA)
- Ankylosing spondylitis (AS)
- Non-radiographic axial spondyloarthritis (nr-axSpA)
- Crohn's disease
- Ulcerative colitis
- Hidradenitis suppurativa (HS) and
- Uveitis.

AMGEVITA contains the active substance adalimumab. Adalimumab is a fully human monoclonal antibody; a protein made by a type of blood cell to fight a foreign protein in the body.

Adalimumab recognises and binds to a specific protein (tumour necrosis factor or TNF-alpha), which is present at higher levels in some inflammatory diseases. By attaching to the target protein, the active substance in AMGEVITA decreases inflammation.

More information about these conditions is provided below and on the page 2.

1. RHEUMATOID ARTHRITIS (RA) is an inflammatory disease of the joints.

   Signs and symptoms of RA include:

   - joint pain
   - tenderness
   - swelling and
   - stiffness.

   AMGEVITA is used to reduce the signs and symptoms of moderate to severely active RA, as well as slow down and protect the joints from further damage.

   AMGEVITA can be used alone or in combination with another medicine called methotrexate to treat RA.

   **Please read the CMI leaflet for methotrexate if you are taking it with AMGEVITA for RA.**

2. POLYARTICULAR JUVENILE ARTHRITIS (pJIA) is an inflammatory disease, involving multiple joints.

   AMGEVITA is used to reduce the signs and symptoms of moderate to severely active disease in patients aged 2 years and older.

3. ENTHESITIS-RELATED ARTHRITIS (ERA) is an inflammatory disease of the joints and the places where tendons attach to bones.

   AMGEVITA is used to treat ERA in children aged 6 years and older.

4. PSORIATIC ARTHRITIS (PsA) is an inflammatory disease of the joints and skin that is usually associated with psoriasis. Signs and symptoms include:

   - joint pain
   - tenderness, and
   - swelling.

   AMGEVITA is used to reduce the signs and symptoms of moderate to severely active disease, and to slow down and protect the joints from further damage.

5. ANKYLOSING SPONDYLITIS (AS) is an inflammatory disease of the spine.

   Signs and symptoms include:

   - back pain and
   - stiffness.

   AMGEVITA is used to reduce the signs and symptoms in patients with active disease.

6. NON-RADIOGRAPHIC AXIAL SPONDYLOARTHRITIS (nr-axSpA) is an autoimmune disease causing arthritis in the spine.

   Unlike AS (above), the inflammation does not show up on an x-ray (radiograph) but may show up on another type of scan called an MRI (magnetic resonance imaging).

   AMGEVITA is used for the treatment of adult patients with severe nr-axSpA.

   Your doctor will check that you have signs of inflammation via a blood test and/or MRI scan.

7. CROHN'S DISEASE (CD) is an inflammatory disease of the digestive tract.

   AMGEVITA is used in children, aged 6 years and older, and adults to reduce the signs and symptoms of moderate to severe Crohn's disease. AMGEVITA is used to bring on and maintain periods where the symptoms are no longer present ("remission").

8. ULCERATIVE COLITIS (UC) is an inflammatory disease of the large intestine (bowel).

   AMGEVITA is used for the treatment of moderate to severe ulcerative colitis in adults and children aged 5 years and older when other medicines are not appropriate.

9. PLAQUE PSORIASIS is an inflammatory disease of the skin that causes red, flaky, itchy, crusty patches of skin covered with silvery scales. It can also affect nails, causing them to crumble, thicken and lift away from the nail bed, which can be painful.

   AMGEVITA is used to treat**:**

   - moderate to severe forms of psoriasis in adults and
   - severe forms in children, aged 4 years and older, and adolescents, who have not responded well enough to other topical or light therapies or who cannot be given those treatments.

10. HIDRADENITIS SUPPURATIVA (HS) is a chronic and inflammatory skin disease, sometimes known as acne inversa.

    Symptoms may include tender nodules (lumps that may look like acne), and abscesses (boils) that might ooze pus. The pus can have an unpleasant odour.

    The condition most commonly affects areas where skin rubs together, such as underneath the breasts, the armpits, inner thighs, groin, or buttocks. Pain and scarring may occur in affected areas.

    AMGEVITA is used for the treatment of adolescents, from 12 years of age, and adults with active moderate to severe HS.

    AMGEVITA can reduce the pain and the number of lumps and boils caused by the disease.

    Your doctor will schedule follow-up appointments to check on your progress to determine whether you should continue treatment.

11. UVEITIS is an inflammatory affecting certain parts of the eye. This inflammation may lead to a decrease of vision and/or the presence of floaters in the eye (black dots or wispy lines that move across the field of vision).

    AMGEVITA is used to treat**:**

    - children from 2 years of age with chronic non-infectious anterior uveitis with inflammation affecting the front of the eye;
    - adults with non-infectious intermediate, posterior and pan-uveitis, with inflammation affecting the back of the eye.

**Ask your doctor if you have any questions about why this medicine has been prescribed for you.**

Your doctor may have prescribed it for another reason.

This medicine is available only with a doctor's prescription.

This medicine is not addictive.

The long-term effects of AMGEVITA on the growth and development of children is not known.

AMGEVITA is a biosimilar medicine with comparable quality, safety, and efficacy to the reference product (Humira®).

## Before you use AMGEVITA

### *When you must not use it*

**Do not use AMGEVITA if you have:**

- An allergy to any medicine containing adalimumab or to any of the ingredients in this medicine (listed at the end of this leaflet).

  Some of the symptoms of an allergic reaction may include:

  – chest tightness

  – shortness of breath, wheezing or difficulty breathing

  – swelling of the face, lips, tongue or other parts of the body

  – skin rash, itching or hives.

- A severe infection, including an infection of the blood (sepsis), active tuberculosis, or other severe infections that can be caused by viruses, fungi, parasites or bacteria.

  Infections can occur when the body's natural defences are lowered.

- Moderate to severe heart failure.

**Do not use this medicine if:**

- You are already using anakinra (Kineret®).

  Anakinra is a medicine used to treat RA, JIA and conditions associated with a defect in a protein called cryopyrin.

- It is after the expiry date printed on the pack; the expiry date refers to the last day of that month, or

- The packaging is torn or shows signs of tampering.

  **Return out of date damaged, or expired medicine to your pharmacist for disposal.**

- AMGEVITA has been shaken or frozen.

- AMGEVITA has been dropped on a hard surface. Part of the AMGEVITA pre-filled syringe/pen may be broken even if you cannot see the break.

  **Use a new AMGEVITA pre-filled syringe/pen if it has been shaken, frozen or dropped on a hard surface.**

**If you are not sure whether you should start taking this medicine, talk to your doctor.**

### *Before you use it*

**Tell your doctor or pharmacist if you have allergies to any other medicines, foods, preservatives or dyes.**

They will want to know if you are prone to allergies.

**Tell your doctor if you have or have ever had any of the following medical conditions:**

- An infection, including a long-term infection in one part of the body (for example, a leg ulcer)

- Infections which keep coming back or other conditions that increase the risk of infections.

  If you are over 65, you may be more likely to get an infection while taking AMGEVITA. It is important that you and your doctor pay special attention to signs of infection while you are being treated with AMGEVITA.

- Tuberculosis ("TB"), or if you have been in close contact with someone who has had it. TB is a contagious and potentially serious infection that mainly affects the lungs.

  As cases of **TB** have been reported in patients treated with AMGEVITA, your doctor will check you for signs and symptoms of **TB** before starting this medicine. This will include a thorough medical examination, including your medical history and appropriate screening tests (for example a chest x-ray and tuberculin test).

  T**B** can develop during therapy even if you have received treatment for the prevention of tuberculosis.

  **Tell your doctor immediately if symptoms of TB or any other infections appear during or after therapy.**

  Symptoms of **TB** may include**:**

  – a cough that doesn't go away

  – weight loss

  – lack of energy, or

  – mild fever.

- Hepatitis B virus (HBV), or if you are a carrier of, or you have active HBV, or you think you might be at risk of contracting HBV.

  In people who carry HBV, AMGEVITA can cause the virus to become active again. In some rare cases, especially if you are taking other medicines that suppress the immune system, reactivation of HBV can be life threatening.

- A fungal infection or have lived or travelled in countries where some fungal infections are common. These infections may develop or become more severe if you use AMGEVITA.

- Uveitis. Your doctor may check for signs and symptoms of neurologic disease before starting this medicine.

- Multiple sclerosis (MS) or other demyelinating diseases (conditions that affect the insulating layer around nerves). Demyelinating disease cause vision loss, muscle weakness, muscle stiffness and spasms, loss of coordination, change in sensation, pain, body functions.

- Allergic reactions such as chest tightness, wheezing, dizziness, swelling or rash

- Blood disorders

- Low resistance to disease

- A serious heart condition

- Any type of cancer

- An autoimmune disease (any condition where the body's immune system mistakenly attacks healthy cells, tissues, or organs).
- A serious lung disease called chronic obstructive pulmonary disease (COPD) that makes breathing difficult
- Kidney disease or other renal problems**.**
- Liver disease, liver damage, or other liver conditions
- Psoriasis and have undergone phototherapy, also known as light therapy
- An allergy to rubber or latex.
  - The needle cover of the pre-filled pen contains natural rubber (latex). The needle cover of the pre-filled syringe does **NOT** contain latex.

**Tell your doctor if you are:**

- Scheduled for any vaccines. Certain vaccines may cause infections and should not be given while receiving AMGEVITA.

  Wherever possible, it is recommended that children be brought up to date with all immunisations according to current immunisation guidelines prior to starting AMGEVITA.

  Patients receiving AMGEVITA should not receive live vaccines.
- Pregnant or plan to become pregnant. A pregnancy study found that there was no higher risk of birth defects when the mother had used AMGEVITA during pregnancy, compared with mothers with the same disease who did not use AMGEVITA.

  If you use this medicine during pregnancy, your baby may have a higher risk of getting an infection.

  **Tell your baby's doctors and other healthcare professionals that you used this medicine during your pregnancy and before your newborn baby receives any vaccine.**
- Breastfeeding or plan to breastfeed.

**If you have not told your doctor or pharmacist about any of the above, tell them before you start using AMGEVITA.**

### *Taking other medicines*

**Tell your doctor or pharmacist if you are taking any other medicines, including any that you buy without a prescription from your pharmacy, supermarket, naturopath or health food shop.**

Some medicines and AMGEVITA may interfere with each other.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while using this medicine.

**Tell your doctor or pharmacist if you are taking:**

- Other biologic medicines used to treat some forms of arthritis, such as:
  - Anakinra (the brand name is Kineret) or
  - Abatacept (the brand name is Orencia).

  Taking either of these two medicines with AMGEVITA may increase the risk of infection.
- Azathioprine or 6-mercaptopurine with AMGEVITA.
- Any medicine that lowers the body's resistance to disease.
- Any other medicines to treat your condition**.** Your doctor may prescribe other medicines for your condition to take with this medicine.

Your doctor may prescribe other medicines to take with AMGEVITA for your condition.

AMGEVITA can be taken together with some medicines such as:

- Methotrexate
- Steroids
- Other disease-modifying anti-rheumatic agents, for example:
  - Sulfasalazine
  - Hydroxychloroquine
  - leflunomide and
  - injectable gold preparations,
- Pain medications including non-steroidal anti-inflammatory drugs (NSAIDS) such as ibuprofen.

## How to use AMGEVITA

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

It may be injected by the patient, family member, guardian, or a carer, but only after proper training in the injection technique.

**Follow all directions given to you by your doctor or pharmacist carefully.**

They may differ from the information contained in this leaflet.

**If you do not understand the instructions on the pack or in this leaflet, ask your doctor or pharmacist for help.**

**Always use AMGEVITA exactly as your doctor has instructed you. Check with your doctor or pharmacist if you are not sure.**

### *How much to use*

**RHEUMATOID ARTHRITIS**

**Adults**

The usual dose for adults with rheumatoid arthritis is one 40 mg injection every fortnight.

If you are not receiving methotrexate with AMGEVITA, your doctor may change your AMGEVITA dose to either 40 mg every week or 80 mg every fortnight, depending on your response.

**PSORIATIC ARTHRITIS (PsA), ANKYLOSING SPONDYLITIS (AS) or NON-RADIOGRAPHIC AXIAL SPONDYLOARTHRITIS (nr-axSpA)**

**Adults**

The usual dose for adults with either PsA, AS or nr-axSpA is 40 mg every fortnight.

**CROHN'S DISEASE**

**Children**

The treatment of Crohn's disease in children should be supported by good nutrition to allow appropriate growth.

The usual dose for children with Crohn's disease depends on the child's body weight.

- **Child with body weight of less than 40 kg**
  - **Initial dose:** 80 mg (given as two 40 mg injections in one day)**.**
  - **Second dose** (2 weeks later): 40 mg**.**
  - **Third dose** (after a further two weeks): 20 mg and **continuing** every fortnight. Your child's doctor may change this ongoing "maintenance" dose from 20 mg every **fortnight** to 20 mg every **week**, depending on your child's response.
- **Child with body weight of 40 kg or above**
  - **Initial dose:** 160 mg (given as four 40 mg injections in one day OR as two 40 mg injections per day for two consecutive days).
  - **Second dose** (2 weeks later): 80 mg (given as two 40 mg injections in one day).
  - **Third dose** (after a further 2 weeks): 40 mg and **continuing** every fortnight. Your child's doctor may change this ongoing "maintenance" dose from 40 mg every **fortnight** to 40 mg every **week** or 80 mg every fortnight, depending on your child's response.

**Adults**

The usual dose for adults with Crohn's disease is**:**

- **Initial dose:** 160 mg (given as four 40 mg injections in one day OR as two 40 mg injections per day over two consecutive days)**.**
- **Second dose** (2 weeks later): 80 mg (given as two 40 mg injections in one day)
- **Third dose** (starting 2 weeks after the second dose**)**: 40 mg and continuing every fortnight. Your doctor may change this ongoing **"**maintenance" dose to 40 mg every week or 80 mg every fortnight depending on your response.

**ULCERATIVE COLITIS**

**Children**

The usual dose for children with ulcerative colitis depends on the child's body weight.

- **Child with body weight of less than 40 kg**
  - **Initial dose:** 80 mg (given as two 40 mg injections in one day).
  - **Second dose (2 weeks later)**: 40 mg.
  - **Third dose (after a further two weeks):** 40 mg every fortnight **OR** 20 mg weekly.
- **Child with body weight of 40 kg or above**
  - **Initial dose:** 160 mg**.**
  - **Second dose (2 weeks later)**: 80 mg**.**
  - **Third dose (after a further 2 weeks):** 80 mg every fortnight **OR** 40 mg weekly.

**Adults**

The usual dose for adults with Crohn's disease is:

- **Initial dose:** 160 mg (given as four 40 mg injections in one day OR as two 40 mg injections per day over two consecutive days)
- **Second dose** (2 weeks later): 80 mg (given as two 40 mg injections in one day)**.**
- **Third dose** (starting 2 weeks after the second dose): 40 mg and continuing every fortnight. Your doctor may change this ongoing "maintenance" dose to 40 mg every week or 80 mg every fortnight depending on your response.

**PSORIASIS**

**Children**

The usual dose for children with psoriasis depends on their body weight.

- **Child with a body weight of less than 30 kg**

  The usual dose for psoriasis is 20 mg given once weekly for the first 2 weeks, then 20 mg every fortnight.
- **Child with a body weight of 30 kg or above**

  The usual dose for psoriasis is 40 mg given once weekly for the first 2 weeks, then 40 mg every fortnight.

**Adults**

The usual dose for adults with psoriasis is:

- **Initial dose:** 80 mg (given as two 40 mg injections in one day).
- **Second dose** (2 weeks later): 40 mg and **continuing** every fortnight. Your doctor may change this ongoing "maintenance" dose to 40 mg every **week** or 80 mg every **fortnight**, depending on your response.

**UVEITIS**

**Children**

The usual dose for children aged 2 years or older with non-infectious anterior uveitis depends on their body weight.

- **Child with a body weight of less than 30 kg**

  The usual dose for uveitis is 20 mg every fortnight used with methotrexate.

  Your child's doctor may also prescribe an initial dose of 40 mg which may be administered one week prior to the start of the usual dose.

- **Child with a body weight of 30 kg or above**

  The usual dose is 40 mg every fortnight used with methotrexate.

  Your child's doctor may also prescribe an initial dose of 80 mg which may be administered one week prior to the start of the usual dose.

**Adults**

The usual dose for adults with uveitis is**:**

- **initial dose:** 80 mg (given as two 40 mg injections in one day).
- **second dose** (2 weeks later): 40 mg and **continuing** every fortnight. Your doctor may change this ongoing "maintenance" dose to 40 mg every **week** or 80 mg every **fortnight**, depending on your response.

**HIDRADENITIS SUPPURATIVA**

**Adolescents from 12 years of age and weighing at least 30 kg**

The usual dose is**:**

- **Initial dose:** 80 mg (given as two 40 mg injections in one day)**.**
- **Second** dose (one week later): 40 mg and **continuing** every fortnight. If you have an inadequate response, your doctor may change this ongoing (maintenance) dose to 40 mg every week or 80 mg every fortnight.

It is recommended that you use an antiseptic wash daily on the affected areas.

**Adults**

The usual dose for adults with HS is**:**

- **Initial dose:** 160 mg (given as four 40 mg injections in one day or two 40 mg injections per day for two consecutive days).
- **Second dose** (2 weeks later): 80 mg (given as two 40 mg injections in one day). After a further 2 weeks, continue with a dose of 40 mg every week or 80 mg every fortnight.

**POLYARTICULAR JUVENILE ARTHRITIS**

**Children 2 years and older**

For children with pJIA, 2 years and older, the usual dose depends on their body weight.

- **Child with a body weight of between 10 kg and less than 30 kg**

  The usual dose is 20 mg given every fortnight.

- **Child with a body weight of 30 kg or above**

  The usual dose is 40 mg given every fortnight.

**ENTHESITIS-RELATED ARTHRITIS**

**Children 6 years and older**

- **Child with a body weight of between 10kg and less than 30 kg**

  The usual dose is 20 mg given every fortnight.

- **Child with a body weight of 30 kg or above**

  The usual dose is 40 mg given every fortnight as a single dose.

## *How to use it*

Instructions for using AMGEVITA sub cutaneous injection are provided in the **Instructions for Use** leaflet supplied in the product pack.

**Read the Instructions for Use carefully and follow them step by step.**

The Instructions for Use explain how to prepare and inject this medicine.

**Do not attempt to inject until you are sure that you understand how to give the AMGEVITA injection to yourself, your child, or your dependent.**

Your doctor or nurse will also show you how best to inject.

**If you do not understand the instructions on the label or in this leaflet, ask your doctor or pharmacist for help.**

More information on how to inject AMGEVITA is available at www.amgevita.co.nz/how-to-inject.

**Always use AMGEVITA exactly as your doctor has instructed you.**

**Check with your doctor, nurse, or pharmacist if you are unsure.**

**Take one tray containing a pre-filled syringe or pen out of the refrigerator.**

**Leave AMGEVITA at room temperature for 15-30 minutes before injecting it.**

**Keep AMGEVITA out of the sight and reach of children.**

**Do not use it if the solution in the syringe or pen is or has been frozen (even if thawed).**

**Do not remove the needle cover or cap while allowing AMGEVITA to reach room temperature.**

**Only use each syringe or pen for one injection.**

**Do not put the cap back on the syringe or pen after injecting AMGEVITA.**

**Put the used AMGEVITA syringe or pen in a sharps disposal container immediately after use.**

### *How long to use it*

**Keep using AMGEVITA for as long as your doctor tells you.**
AMGEVITA will not cure your condition but will help control the symptoms.

**Ask your doctor if you are not sure how long you or your child need to use this medicine for.**

### *If you forget to use it*

**If you forget to give an injection, you should inject the missed dose of AMGEVITA as soon as you remember. Then inject the next dose as you would have on the originally scheduled day.**

**Do not try to make up for missed doses by injecting more than one dose at a time.**

**If it is almost time for the next dose, skip the missed dose, and inject the next dose when you are meant to.**

**If you are not sure what to do, ask your doctor or pharmacist.**

### *If you take too much (overdose)*

**If you accidentally inject AMGEVITA more frequently than prescribed by the doctor, immediately telephone your doctor or the National Poisons Centre (0800 POISON or 0800 764 766) or go to Accident and Emergency at the nearest hospital.**

**Do this even if there are no signs of discomfort or poisoning.**

You/the patient may need urgent medical attention.

**Always take the outer carton of the medicine with you, even if it is empty.**

## While you are using AMGEVITA

### *Things you must do*

**Check with your doctor before you or your child (if applicable) receive any vaccines.**

Wherever possible, it is recommended that children be brought up to date with all immunisations according to current immunisation guidelines prior to starting on AMGEVITA therapy.

Patients receiving AMGEVITA should not receive live vaccines (for example, BCG or oral polio vaccine).

**If you become pregnant while using AMGEVITA, tell your doctor immediately.**

**If you are about to be started on any new medicine, tell your healthcare provider that you are using AMGEVITA.**

**Tell all doctors, dentists, and pharmacists who are treating you that you are using AMGEVITA.**

**If you are going to have surgery, tell all your doctors that you are using AMGEVITA.**

Your doctor may recommend temporary discontinuation of AMGEVITA.

**Keep all your doctor's appointments so that your progress can be checked.**

### *Things you must not do*

**Do not warm AMGEVITA in any way. For example, do not warm it in a microwave or in hot water.**

**Do not shake or drop the pre-filled syringe or pre-filled pen.**

**Do not give AMGEVITA to anyone else, even if they have the same condition as you.**

**Do not use AMGEVITA to treat any other complaints unless your doctor tells you to.**

**Do not stop using AMGEVITA without checking with the doctor.**

**Do not take AMGEVITA in combination with either anakinra (Kineret) or abatacept (Orencia).**

Taking either of these two medicines with AMGEVITA may lead to an increased risk of developing a serious infection.

**Do not change the dose unless the doctor tells you to.**

### *Things to be careful of*

**Tell your doctor if you get symptoms of an infection such as a fever, skin sores, feeling tired or any problems with your teeth and gums.**

You might get infections more easily while you are receiving AMGEVITA treatment. These infections may be serious and include:

- Tuberculosis (TB)
- Infections caused by viruses, fungi, parasites or bacteria
- Sepsis (an infection of the blood, that may, in rare cases, be life-threatening), or
- Other infections.

Your doctor may recommend you discontinue AMGEVITA if you develop an infection.

**Be careful driving or operating machinery until you know how AMGEVITA affects you.**

The effects on your ability to drive and use machines whilst taking AMGEVITA are not known.

## Side effects

**Tell your doctor as soon as possible if you do not feel well while you are taking AMGEVITA or if you have any other problems using it.**

**Do this even if you do not think the problems are connected to the medicine or are not listed in this leaflet.**

All medicines can have unwanted side effects. Sometimes they are serious, most of the time they are not.

You may need medical attention if you get some side effects.

**Do not be alarmed by the following lists of possible side effects.**

You may not experience any of them.

**Ask your doctor or pharmacist any questions you may have.**

**Tell your doctor immediately or go to Accident and Emergency at your nearest hospital if you experience any of the following side effects:**

- Signs of an allergic reaction such as:
  - Chest tightness
  - Shortness of breath, wheezing or difficulty breathing
  - Swelling of the face, lips, tongue, or other parts of the body
  - Hives, itching or skin rash.
- Signs and symptoms of heart failure such as:
  - shortness of breath with exertion or upon lying down or
  - swelling of the feet.
- Signs and symptoms suggestive of a blood disorder such as:
  - Persistent fever
  - Bruising
  - Bleeding very easily, or
  - Paleness.
- Signs suggesting a blood clot, such as:
  - Swelling, tenderness, redness and a warm feeling of an area of the arm or leg.

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation.

**Tell your doctor as soon as possible if you notice any of the following side effects:**

- Signs of tuberculosis (TB) such as:
  - Persistent cough
  - Weight loss
  - Listlessness
  - Fever.
- Signs of infection such as:
  - Fever
  - Lack of energy
  - Skin sores
  - Problems with your teeth or gums
  - Burning when you pass urine.

You might get infections more easily while you are receiving AMGEVITA treatment.

- Signs of nervous system disorders such as:
  - Numbness or tingling throughout your body
  - Weakness in your arm or leg
  - Double vision.
- Signs of soft tissue infection such as a bump or open sore that doesn't heal.

The above list includes serious side effects. You may need urgent medical attention.

**Tell your doctor if you notice any of the following common side effects and they worry you:**

- Pain, swelling, redness or itching at the site of injection
- Cold, runny nose, sinus infection, sore throat, cough, congestion on the chest, asthma, or a worsening of asthma symptoms
- Lower respiratory tract infections (such as bronchitis, pneumonia)
- Pain in the ear which could suggest an ear infection
- Pain or inflammation of the eye or eye lid or changes to your vision
- Mouth ulcers, pain, or excessive bleeding from the gums
- Burning or pain when passing urine, or blood in the urine
- Skin bumps or sores that don't heal
- Headache or migraine, dizziness, vertigo
- Muscle weakness or numbness, difficulty balancing
- Fever, flushing, increased sweating
- Nausea, vomiting, abdominal pain
- Reflux or heartburn
- Chest pain
- Rash, itching, redness or scaly patches
- Problems with your finger or toenails
- Hair loss
- Fatigue, tiredness, lack of energy
- Muscle, joint or bone pain
- Bleeding or bruising more easily than usual
- Feeling overwhelmed or sad, or lacking motivation (depression)
- Feeling anxious, especially fearful or worried (anxiety)
- Feeling like your heart is beating faster
- Viral infections (including the flu, cold sore blisters, chicken pox and shingles)
- Bacterial infections (including urinary tract infection)
- Fungal infections.

The above list includes the more common side effects of AMGEVITA. They are usually mild and short-lived.

There have been cases of certain kinds of cancer in patients using AMGEVITA or similar medicines.

People with more serious RA that have had the disease for a long time may have a higher chance of getting a kind of cancer that affects the lymph system, called lymphoma, or that affects the blood, called leukaemia. If you take AMGEVITA your risk may increase.

On rare occasions, a specific and severe type of lymphoma has been observed in patients taking AMGEVITA.

**Tell your doctor if new skin lesions (skin spots or sores) appear or if**

**existing lesions change appearance during or after AMGEVITA treatment.**

Very rare cases of skin cancer have been observed in patients taking AMGEVITA.

**If you have COPD, or are a heavy smoker, discuss with your doctor whether treatment with a TNF blocker is appropriate for you.**

There have been cases of cancers other than lymphoma in patients with a specific type of lung disease called Chronic Obstructive Pulmonary Disease (COPD) treated with another TNF blocker.

**Tell your doctor of pharmacist if you notice anything else that is making you feel unwell.**

Other side effects not listed above may occur in some people.

**Laboratory results**

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

These include:

- Increased lipids
- Increased uric acid
- Elevated liver enzymes.

# After using AMGEVITA

## *Storage*

**Keep AMGEVITA in:**

- the pack until it is time to use it. This will protect it from light.
- a refrigerator (2°C-8°C). Do not freeze it.
- the refrigerator in a way that children cannot get to it.

**Keep AMGEVITA at the right temperature when you travel.**

This is important whether travelling by car, bus, train, plane or any other form of transport.

**When needed, you can store one AMGEVITA syringe or pen at room temperature (below 25°C) for a maximum period of 14 days. Protect it from light.**

Once removed from the refrigerator and stored at room temperature, the medicine must be used within 14 days or discarded (see Disposal).

**Do this even if it has been returned to the refrigerator.**

**Write down the date you first remove the syringe or pen from the refrigerator on the Instructions for Use (pack leaflet), so you can check how long it has been stored out of the refrigerator.**

These storage instructions are also important while travelling.

## *Disposal*

**After injecting AMGEVITA, immediately throw away the used pre-filled syringe or pre-filled pen in a special "sharps" container as instructed by your doctor, nurse or pharmacist.**

**Keep the sharps container out of reach and sight of children.**

**Ask your pharmacist what to do with any AMGEVITA that is left over if your doctor tells you to stop taking it.**

# Product description

## *What AMGEVITA looks like*

AMGEVITA is a clear, colourless, sterile solution. It is adjusted to pH 5.2.

AMGEVITA is available in the following strengths and pack sizes:

- One 20 mg/0.4 mL pre-filled syringe.
- Two 40 mg/0.8 mL pre-filled syringes.
- Two 40 mg/0.8 mL pre-filled SureClick pens.

## *Ingredients*

AMGEVITA contains adalimumab 50 mg/mL as the active ingredient. It also contains the following inactive ingredients:

- Glacial acetic acid (E260)
- Polysorbate 80 (E433)
- Sodium hydroxide (E524)
- Sucrose
- Water for injections.

AMGEVITA does **not** contain any:

- antimicrobial preservatives
- lactose
- gluten
- tartrazine or other azo dyes.

## *Support*

Resources are available for patients in New Zealand who are prescribed AMGEVITA including:

- Instructional videos to help with injection
- Sharps disposal bin order form
- Reminder leaflets
- Frequently asked questions document
- Nurse support.

For further information, visit www.amgevita.co.nz/.

## *Sponsor*

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