AMGEVITA®

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using AMGEVITA?

AMGEVITA pre-filled syringes and pre-filled SureClick® pens contain the active ingredient adalimumab. AMGEVITA is used to treat various inflammatory conditions.

For more information, see Section 1. Why am I using AMGEVITA? in the full CMI.

2. What should I know before I use AMGEVITA?

Read this leaflet carefully before you use AMGEVITA and keep it with the medicine.

Check the list of ingredients at the end of the CMI. Do not use AMGEVITA if you have ever had an allergic reaction to any of the ingredients.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section 2. What should I know before I use AMGEVITA? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with AMGEVITA and affect how it works. AMGEVITA may interfere with other medicines and how they work.

A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. How do I use AMGEVITA?

AMGEVITA is injected under the skin (subcutaneous).

More instructions can be found in Section 4. How do I use AMGEVITA? in the full CMI.

5. What should I know while using AMGEVITA?

Things you should do	• Remind any doctor, dentist or pharmacist you visit that you are using AMGEVITA. • Keep all your appointments, including those for blood tests. • Tell your doctor if you develop an infection or you notice new or changed spots on your skin. • Talk to your doctor if you are scheduled for any vaccines.
Things you should not do	• Do not stop using AMGEVITA suddenly or change the dose unless your doctor tells you to.
Driving or using machines	• Be careful before you drive or use any machines until you know how AMGEVITA affects you. • The effects on your ability to drive or use machines whilst taking AMGEVITA are not known.
Drinking alcohol	• There is no information on the effects of taking AMGEVITA with alcohol.
Looking after your medicine	• Store AMGEVITA in the refrigerator (2°C to 8°C). Do not freeze. • Keep AMGEVITA pens or syringes in the original pack to protect your medicine from light.

For more information, see Section 5. What should I know while using AMGEVITA? in the full CMI.

6. Are there any side effects?

Side effects that require urgent medical attention include: signs of an allergic reaction, such as chest tightness, difficulty breathing, swelling of face lips and tongue, rash; signs of heart failure, such as shortness of breath on exertion or lying down, swelling of the feet; signs suggesting a blood disorder, such as persistent fever, bruising, bleeding, paleness.

For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

AMGEVITA® (am-jeh-vee'-tah)

Active ingredient(s): *adalimumab* (ada-lim-u-mab)

Consumer Medicine Information (CMI)

This leaflet provides important information about using AMGEVITA. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using AMGEVITA.**

Where to find information in this leaflet:

1. Why am I using AMGEVITA?
2. What should I know before I use AMGEVITA?
3. What if I am taking other medicines?
4. How do I use AMGEVITA?
5. What should I know while using AMGEVITA?
6. Are there any side effects?
7. Product details

1. Why am I using AMGEVITA?

AMGEVITA contains the active ingredient adalimumab. AMGEVITA is a biosimilar medicine. It has been assessed to be as safe and effective as the reference product and provides the same health outcomes.

AMGEVITA is used to treat any of the following inflammatory conditions (listed in alphabetical order):

- Ankylosing spondylitis
- Crohn's disease in adults and children aged 6 years and over
- Enthesitis-related arthritis
- Hidradenitis suppurativa in adults and adolescents aged 12 years and over
- Polyarticular juvenile idiopathic arthritis
- Psoriasis in adults and children aged 4 years and over
- Psoriatic arthritis
- Rheumatoid arthritis
- Ulcerative colitis, and
- Uveitis.

2. What should I know before I use AMGEVITA?

Warnings

Do not use AMGEVITA if any of the following apply:

- You are allergic to adalimumab or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use it.
- You have a severe infection such as sepsis (a serious infection of the blood), tuberculosis (a serious infection of the lungs caused by bacteria), or other severe infection, caused by a virus, fungus, parasite or bacteria.
- You have heart failure considered by your doctor to be moderate or severe.

Check with your doctor if you have:

- Any vaccinations scheduled
- Any surgery planned
- A lung disease called chronic obstructive pulmonary disease (COPD)
- A disease that affects the insulating layer of the nerves, e.g. multiple sclerosis (MS)
- Current active hepatitis B, have ever had hepatitis B, are a carrier of the hepatitis B virus or you think you may be at risk of contracting hepatitis B
- Ever had tuberculosis, or you have been in close contact with someone who has tuberculosis. Tuberculosis can develop during therapy even if you have received treatment for the prevention of tuberculosis.

Check with your doctor if you have or have had:

- An infection that does not go away or keeps coming back, this can include leg ulcers
- An infection caused by a fungus, or you have lived or travelled in countries where fungal infections are common
- Uveitis, where the middle layer of the eyeball is inflamed
- Allergic reactions such as chest tightness, wheezing, dizziness, swelling or rash
- A blood disorder
- Low resistance to disease
- A heart condition
- Cancer or autoimmune disease
- Kidney problems
- Liver problems
- Psoriasis (a skin disease that produces patches of thickened, scaly skin that is not contagious)
- Phototherapy, also known as light therapy, for psoriasis.

Check with your doctor if you take any medicines for any other condition.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. Are there any side effects?

Pregnancy

Make sure your doctor knows if you are pregnant or intend to become pregnant. AMGEVITA should only be used in pregnancy if clearly needed.

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

You should consider the use of effective contraception to prevent pregnancy and continue its use for at least 5 months after the last AMGEVITA injection.

Tell your baby's doctors if you have taken AMGEVITA while you are pregnant, especially before your baby receives any vaccinations.

Breastfeeding

Make sure your doctor knows if you are breastfeeding or intend to breastfeed.

Use in children

Wherever possible, it is recommended that children are up to date with all vaccinations, according to current immunisation guidelines, before they are started on AMGEVITA treatment.

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

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

Use in the elderly

If you are over 65, you may be more likely to get an infection while taking AMGEVITA.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other:

- medicines
- vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with AMGEVITA and affect how it works.

Do not take AMGEVITA if you are taking the following medicine:

- anakinra, a medicine used to treat rheumatoid arthritis, juvenile idiopathic arthritis and conditions associated with a defect in a protein called cryopyrin.

Medicines that may increase the risk of infections when taken with AMGEVITA include:

- anakinra
- abatacept, a medicine used to treat rheumatoid arthritis, polyarticular juvenile idiopathic arthritis, psoriatic arthritis
- azathioprine, a medicine used for suppressing the immune system to treat various conditions
- 6-mercaptopurine, a medicine used to treat certain types of leukaemia (a blood disorder).

AMGEVITA may affect how other medicines that you take work.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect AMGEVITA.

4. How do I use AMGEVITA?

How much to use

Doses for each condition are given in the following text (in alphabetic order).

For 160 mg and 80 mg doses, please also see Special dosing instructions **(at the end of Section 4).**

Ankylosing spondylitis in adults

- Inject one 40 mg dose every fortnight.

Crohn's disease in adults

- Inject 160 mg on day 1, followed by 80 mg on day 15 and 40 mg on day 29.
- Then, continue to inject 40 mg every fortnight (maintenance dose). Your doctor may change the maintenance dose to 40 mg every week, or 80 mg every fortnight, depending on your response.

Crohn's disease in children

If the patient's body weight is at least 40 kg:

- Inject 160 mg on day 1, followed by 80 mg on day 15 and 40 mg on day 29.
- Then, continue to inject 40 mg every fortnight (maintenance dose). Your doctor may change this maintenance dose to 40 mg every week, or 80 mg every fortnight, depending on your response.

If the patient's body weight is less than 40 kg:

- Inject 80 mg on day 1, followed by 40 mg on day 15, and 20 mg on day 29.
- Then, continue to inject 20 mg every fortnight. Your doctor may change this maintenance dose to 20 mg every week, depending on your response.

Enthesitis-related arthritis

If the patient's body weight is at least 30 kg:

- Inject one 40 mg dose every fortnight.

If the patient's body weight is between 10 and 30 kg:

- Inject one 20 mg dose every fortnight.

Hidradenitis suppurativa in adults

- Inject 160 mg on day 1, followed by 80 mg on day 15.
- Then continue to inject 40 mg every week or 80 mg every fortnight from day 29 (maintenance dose).

Hidradenitis suppurativa (HS) in adolescents

- Inject 80 mg on day 1, followed by 40 mg on day 8, and 40 mg on day 22.
- Then continue to inject 40 mg every fortnight (maintenance dose). Your doctor may change this maintenance dose to 40 mg every week, or 80 mg every fortnight depending on your response.

Use an antiseptic face wash on the affected areas.

Polyarticular juvenile idiopathic arthritis

If the patient's body weight is at least 30 kg:

- Inject one 40 mg dose every fortnight.

If the patient's body weight is between 10 and 30 kg:

- Inject one 20 mg dose every fortnight.

Psoriasis in adults

- Inject 80 mg on day 1, followed by 40 mg on day 8 and 40 mg on day 22.
- Then, continue to inject 40 mg every fortnight (maintenance dose). Your doctor may change this maintenance dose to 40 mg every week, or 80 mg every fortnight, depending on your response.

Psoriasis in children

If the patient's body weight is at least 40 kg:

- Inject 40 mg on day 1, followed by 40 mg on day 8 and 40 mg on day 22.
- Then continue to inject 40 mg every fortnight (maintenance dose).

If the patient's body weight is less than 40 kg:

- Inject 20 mg on day 1, inject 20 mg on day 8, then 20 mg on day 22.
- Then continue to inject 20 mg every fortnight (maintenance dose).

Psoriatic arthritis in adults

- Inject one 40 mg dose every fortnight.

Rheumatoid arthritis in adults

- Inject one 40 mg dose every fortnight.

If you are **not taking methotrexate**, your doctor may change this dose to 40 mg every week, or 80 mg every fortnight, depending on your response.

Ulcerative colitis in adults

- Inject 160 mg on day 1, followed by 80 mg on day 15 and 40 mg on day 29.
- Then, continue to inject 40 mg every fortnight (maintenance dose). Your doctor may change this maintenance dose to 40 mg every week, or 80 mg every fortnight, depending on your response.

Uveitis in adults

- Inject 80 mg on day 1, followed by 40 mg on day 8 and 40 mg on day 22. Then continue to inject 40 mg every fortnight (maintenance dose).

Special dosing instructions

- **80 mg dose** can be given as one 80 mg injection or two 40 mg injections in one day.
- **160 mg dose** can be given as any one of the following:
    - o two 80 mg injections in one day, or
    - o four 40 mg injections in one day, or
    - o one 80 mg injection per day over 2 consecutive days, or
    - o two 40 mg injections per day over 2 consecutive days.

Some patients may need to use AMGEVITA and take other medicines. Your doctor will tell you which medicines to take, how to take them, and how long to take them.

How to use AMGEVITA

Read the Instructions for Use that are supplied in the pack, with the product, before preparing and using an AMGEVITA injection.

AMGEVITA is injected under the skin (subcutaneous). An injection should not be attempted until proper training has been received on the correct injection technique.

AMGEVITA can be injected by the patient, or by someone else, such as a family member, friend or carer.

Do not mix the solution for injection with any other medicine.

If you forget to use AMGEVITA

It is important that you use your medicine as prescribed by your doctor.

If you miss your dose at the usual time, inject AMGEVITA as soon as you remember, and continue injecting the next dose at the usual time on your scheduled day.

Do not take a double dose to make up for the dose you missed.

If you inject too much AMGEVITA

If you think that you have used too much AMGEVITA, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

Always take the outer carton of the medicine with you.

5. What should I know while using AMGEVITA?

Things you should do

- AMGEVITA should be used regularly, as prescribed by your doctor.
- Follow all instructions given to you and use AMGEVITA until your doctor tells you to stop.
- Keep all your doctor's appointments so your progress can be tracked.
- Keep your appointments for blood tests. Some side effects are seen in blood results before you have any symptoms.
- Check with your doctor before you receive any vaccines.
- Remind any healthcare professional you visit that you are using AMGEVITA, especially if you are scheduled for surgery or to receive any live vaccines (e.g. Bacille Calmette-Guerin or oral polio vaccine).

Call your doctor straight away if you:

- Get symptoms of an infection, such as a fever, skin sores, feeling tired, any problems with your teeth or gums or pain when passing urine or blood in your urine.
- Become pregnant while using AMGEVITA.

- Notice new skin lesions (skin spots or sores), or if existing lesions change appearance.

Things you should not do

Do not stop using this medicine or change the dose without checking with your doctor.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how AMGEVITA affects you.

Drinking alcohol

There is no information on the use of alcohol with AMGEVITA.

Looking after your medicine

Follow the instructions on the AMGEVITA carton for instructions on how to take care of your medicine properly.

Keep AMGEVITA in a refrigerator (at 2°C to 8°C). Do not freeze. Keep it in the carton protected from light.

Keep it where children cannot reach it.

When necessary, AMGEVITA may be stored at room temperature (25°C) for a maximum of 14 days, protected from light.

Once removed from the refrigerator, each pen or syringe must be used within 14 days or discarded, even if it has been returned to the refrigerator.

When to discard your medicine

After injecting AMGEVITA, immediately throw away the used syringe or pen into a special sharps container.

Discard any AMGEVITA that has been removed from the refrigerator for more than 14 days.

Getting rid of any unwanted medicine

If your doctor advises that you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
Injection site: • pain • swelling • redness • itching	**Speak to your doctor if you have any of these less serious side effects and they worry you.**
Lungs and upper airways: • cold • flu • runny nose • cough • sore throat • sinus infection • asthma or worsening of asthma • bronchitis, pneumonia (congestion on the chest) **Ears, eyes, and mouth:** • ear pain • pain, redness or swelling of the eye or eye lid • changes in vision • mouth ulcers • gum pain • excessive bleeding from the gums **Brain and nerves:** • headache or migraine • dizziness • muscle weakness • muscle, bone or joint pain • numbness • difficulty balancing **Gut and digestion:** • nausea • vomiting • tummy pain • reflux or heartburn **Skin and nails:** • rash • itching • redness • scaly skin patches • problems with your fingernails or toenails • hair loss • cold sore blisters • chicken pox **Blood:** • bleeding • bruising more easily than usual **Body as a whole:** • tiredness • chest pain • lack of energy • increased heart rate	**Speak to your doctor if you have any of these less serious side effects and they worry you.**

Less serious side effects	What to do
• feeling overwhelmed or sad, lacking motivation (depression) • feeling especially fearful or worried (anxiety)	

More serious side effects

More serious side effects	What to do
Signs of tuberculosis: • persistent cough • weight loss • listlessness (lack of energy) • fever **Signs of an infection, such as:** • fever • lack of energy • skin bump or sore that doesn't heal • problems with your teeth or gums • pain when passing urine or blood in the urine. **Signs of kidney stones:** • pain from your side or back to your groin, difficulty passing urine or blood in your urine. **Signs of problems with your nervous system, such as:** • numbness • tingling throughout your body • arm or leg weakness • double or blurred vision. **Signs suggesting a blood clot, such as:** • swelling, tenderness, redness and a warm feeling of an area of the arm or leg	**Speak to your doctor as soon as possible if you notice any of these more serious side effects.**

Very serious side effects

Serious side effects	What to do
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 of heart failure, such as:** • shortness of breath on exertion or lying down • swelling of the feet.	**Call your doctor urgently or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.**
Signs suggesting a blood disorder, such as: • persistent fever • bruising • bleeding very easily • paleness.	

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

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

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at https://www.tga.gov.au/safety/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

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

What AMGEVITA contains

AMGEVITA comes in two different concentrations:

AMGEVITA 20 mg in 0.4mL and 40 mg in 0.8mL (50mg/mL)

AMGEVITA is a clear, colourless, sterile solution containing:

- adalimumab 20 mg in 0.4 mL solution in a pre-filled syringe (AUST R 278702)
- adalimumab 40 mg in 0.8 mL solution in a pre-filled syringe (AUST R 278701)
- adalimumab 40 mg in 0.8 mL solution in a pre-filled SureClick® pen (AUST R 273536).

Active ingredient (main ingredient)	• adalimumab
Other ingredients (inactive ingredients)	• glacial acetic acid (E260) • polysorbate 80 (E433) • sodium hydroxide (E524) • sucrose • water for Injections

Do not take this medicine if you are allergic to any of these ingredients.

AMGEVITA 20 mg in 0.2mL, 40mg in 0.4mL and 80mg in 0.8mL (100mg/mL)

AMGEVITA is a clear, colourless, sterile solution containing:

- adalimumab 20 mg in 0.2 mL solution in a pre-filled syringe (AUST R 484565)

- adalimumab 40 mg in 0.4 mL solution in a pre-filled syringe (AUST R 484554)
- adalimumab 40 mg in 0.4 mL solution in a pre-filled SureClick® pen (AUST R 484553)
- adalimumab 80 mg in 0.8 mL solution in a pre-filled SureClick® pen (AUST R 486685).

Active ingredient (main ingredient)	• adalimumab
Other ingredients (inactive ingredients)	• s-lactic acid • polysorbate 80 (E433) • sodium hydroxide (E524) • sucrose • water for Injections

Do not take this medicine if you are allergic to any of these ingredients.

What AMGEVITA looks like

AMGEVITA comes in two different concentrations:

AMGEVITA 20 mg in 0.4mL and 40 mg in 0.8mL (50mg/mL)

- AMGEVITA 20 mg (in 0.4 mL) pre-filled syringe in packs containing 1 or 2 pre-filled syringe(s).
- AMGEVITA 40 mg (in 0.8 mL) pre-filled syringe in packs containing 1, 2, 4 or 6 pre-filled syringe(s).
- AMGEVITA 40 mg (in 0.8 mL) pre-filled SureClick® pen in packs containing 1, 2, 4 or 6 pre-filled SureClick® pen(s).

AMGEVITA 20 mg in 0.2mL, 40mg in 0.4mL and 80mg in 0.8mL (100mg/mL)

- AMGEVITA 20 mg (in 0.2 mL) pre-filled syringe in packs containing 1 pre-filled syringe.
- AMGEVITA 40 mg (in 0.4 mL) pre-filled syringe in packs containing 2 pre-filled syringes.
- AMGEVITA 40 mg (in 0.4 mL) pre-filled SureClick® pen in packs containing 1 or 2 pre-filled SureClick® pen(s).
- AMGEVITA 80 mg (in 0.8 mL) pre-filled SureClick® pen in packs containing 1 pre-filled SureClick® pen.

Not all presentations may be available or marketed in all pack sizes.

Who distributes AMGEVITA

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www.amgenmedinfo.com.au

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Version information

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