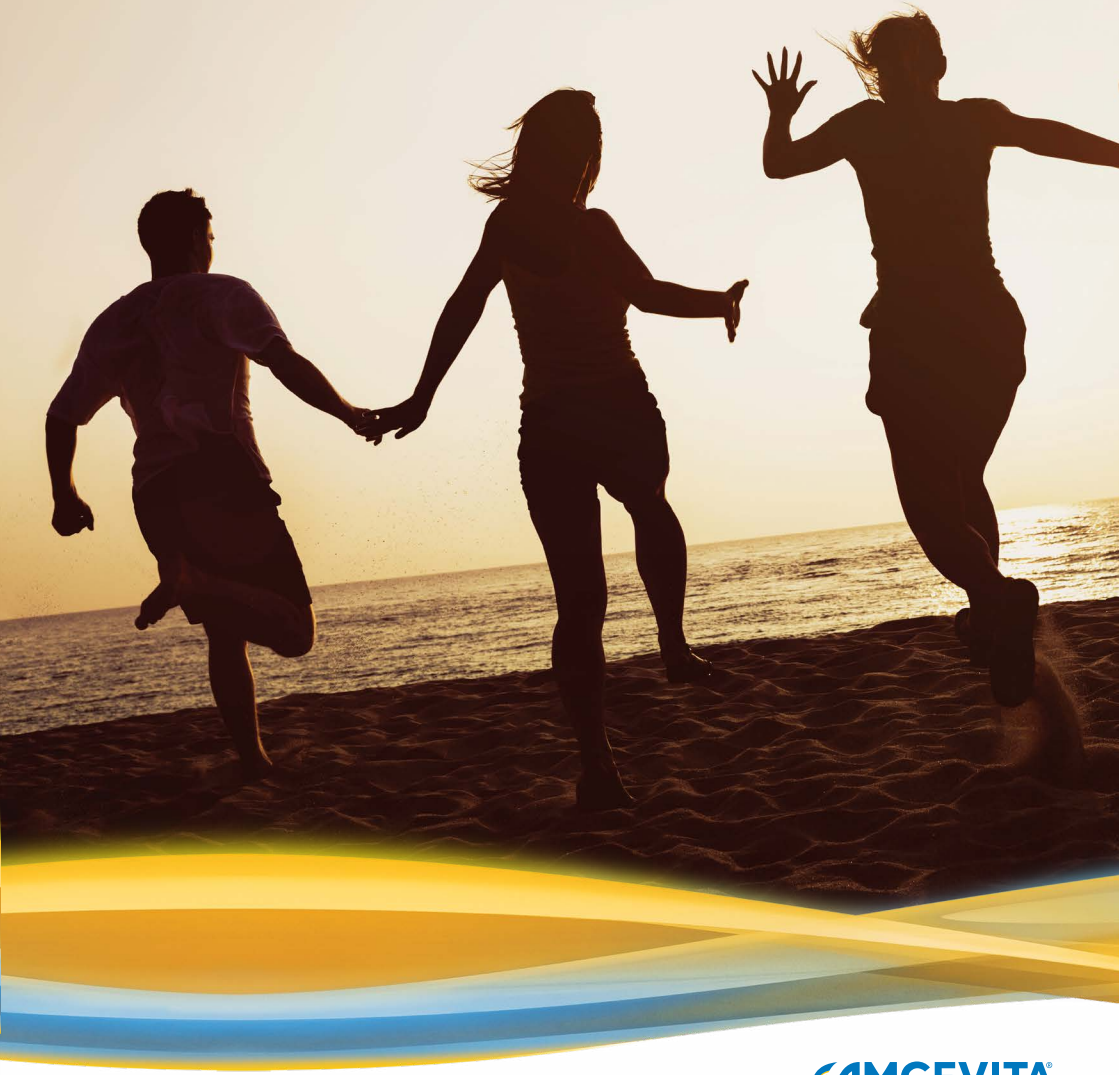
AMGEN®

What you need to know about AMGEVITA® (adalimumab)



Visit *amgevita.co.nz* to access support materials

AMGEVITA® (adalimumab)

This booklet is for people who have been prescribed AMGEVITA by their doctor. This booklet should be read in conjunction with the AMGEVITA Consumer Medicine Information (CMI) available from your pharmacist or by visiting **www.medsafe.govt.nz**

If you have any questions speak to your healthcare provider.

For more information on AMGEVITA or to report a side effect involving AMGEVITA or product complaint contact Amgen Medical Information on **0800 443 885** or **email: medinfo.JAPAC@amgen.com**

What is AMGEVITA and how does it work?[1,2]

AMGEVITA contains adalimumab – a biologic medicine that acts on the immune system to reduce inflammation and is used to treat inflammatory conditions.

AMGEVITA is a biosimilar medicine, meaning it is highly similar to the original adalimumab medicine.

AMGEVITA has been assessed to be as safe and effective as the original adalimumab medicine at treating certain inflammatory conditions.

Why am I using AMGEVITA?[1]

AMGEVITA is used to treat the following inflammatory conditions. Your doctor has prescribed AMGEVITA to help manage one of these 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)
- Uveitis.

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.

What should I know before I use AMGEVITA?[1]

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

Before you start treatment you should tell your doctor if you:

- Have any other medical conditions.
- Take any other medicines (including over-the-counter supplements).
- Are pregnant, or are planning a pregnancy.
- Have an infection, including a long-term infection in one part of the body (e.g. a leg ulcer).
- Have or have had a blood disorder, heart condition, low resistance to disease, a serious heart condition, any type of cancer, kidney or liver problems, and any other previous health issues.
- Have a nervous system disease, e.g. multiple sclerosis.
- Have any vaccinations or surgery planned.
- Have ever had tuberculosis (TB) or been in close contact with someone who has TB.
- Have chronic obstructive pulmonary disease, are a carrier of hepatitis B virus or have active hepatitis B.
- Have an allergy to rubber or latex

You should NOT USE AMGEVITA if you are allergic to adalimumab or the other ingredients listed in the product, if you have moderate or severe heart failure, or if you have any kind of severe infection (such as sepsis, tuberculosis, or other severe infections that can be caused by viruses, fungi, parasites or bacteria).[1]

The CMI, available from your pharmacist or at www.medsafe.govt.nz, provides more detailed information about AMGEVITA. Please read the information carefully, and if you have questions or concerns, speak to your doctor, nurse or pharmacist.

What if I'm taking other medicines?[1]

It's very important to 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 may interfere with AMGEVITA and affect how it works or increase the risk of infections when taken with AMGEVITA. Do not take AMGEVITA in combination with either anakinra (Kineret®) or abatacept (Orencia®).

You will find a full list of these medicines in the CMI.

How do I use AMGEVITA?[1]

AMGEVITA is injected under the skin. It may be injected by you, or your family member, guardian or carer, using the SureClick pre-filled pen or the pre-filled syringe after receiving training. For more information and step-by-step instructions on use of the SureClick pre-filled pen, refer to the instructions for use on the following pages. You can also visit amgevita.co.nz to view instructional videos and find instructions for use of the SureClick pre-filled pen and pre-filled syringe.

What else should I do while using AMGEVITA?[1]

Your doctor will give you instructions on the right dose for your condition. It is important that you use your medicine as prescribed by your doctor. If you miss your dose, inject 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.

You SHOULD:

- Not stop using AMGEVITA without checking with your doctor.
- Keep all your doctor's appointments so that your progress can be checked.
- Check with your doctor before you or your child (if applicable) receive any vaccines, or if you are going to have surgery.
- Tell your healthcare provider that you are using AMGEVITA if you are about to be started on any new medicine.

You SHOULD NOT:

Change your dose or stop your therapy unless your doctor tells you to.

How should I store AMGEVITA?[1]

AMGEVITA should be stored in a refrigerator at 2°C to 8°C and should not be frozen. Keep it in the pack protected from light in a place where children cannot reach it.

When necessary (e.g. if you are travelling), AMGEVITA may be stored at room temperature (below 25°C) protected from light for a maximum of 14 days. After 14 days it must be discarded even if it has been returned to the refrigerator.

What are the possible side effects?[1]

During treatment with AMGEVITA you may be at risk for certain side effects, including infections. It's important you understand these side effects and can monitor for them.

All medicines can have unwanted side effects. Sometimes they are serious, most of the time they are not. Some side effects observed with AMGEVITA may not have symptoms and might only be discovered through blood tests.

Some side effects require urgent medical attention, including:[1]

- **Signs of an allergic reaction** – chest tightness, difficulty breathing, swelling of the face, lips and tongue, rash, hives and itching.
- **Signs of heart failure** – shortness of breath on exertion or when lying down, or swelling of the feet.
- **Signs of infection** – fever, lack of energy, skin sores, problems with your teeth and gums, or burning when you pass urine.
- **Nervous system problems** – numbness or tingling, vision changes or weakness in your arm or leg.
- **Signs of a blood disorder** – persistent fever, bruising, easy bleeding, or paleness.
- **Signs of TB** – persistent cough, weight loss, listlessness (lack of energy), or fever.
- **Signs of soft tissue infection** – a bump or open sore that doesn't heal.

This is not a full list of the possible side effects that can occur. Please read the AMGEVITA CMI for more information and tell your doctor right away if you feel anything unusual during treatment with AMGEVITA.

INSTRUCTIONS FOR USE: AMGEVITA SINGLE USE SURECLICK® PRE-FILLED PEN[3]

Please refer to the GUIDE TO PARTS as you move through the steps.

STEP 1: PREPARE

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

- Carefully lift the SureClick pre-filled pen straight up out of the box.
- Put the original package with any unused SureClick pre-filled pens back in the refrigerator.
- For a more comfortable injection, leave the SureClick pre-filled pen at room temperature for **15 to 30** minutes before injecting.

⦸ **Do not**

✘ Put the SureClick pre-filled pen back in the refrigerator once it has reached room temperature.

✘ Try to warm the SureClick pre-filled pen by using a heat source such as hot water or microwave.

✘ Leave the pre-filled pen in direct sunlight.

✘ Shake the SureClick pre-filled pen.

✘ Remove the yellow cap from the SureClick pre-filled pen yet.

B Inspect the AMGEVITA SureClick pre-filled pen.

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

⦸ **Do not** use the SureClick pre-filled pen if:

✘ The medicine is cloudy or discoloured, or contains flakes or particles.

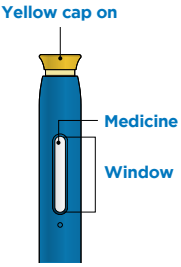
✘ Any part appears cracked or broken.

✘ The SureClick pre-filled pen has been dropped on a hard surface.

✘ The yellow cap is missing or not securely attached.

✘ The expiry date printed on the label has passed.

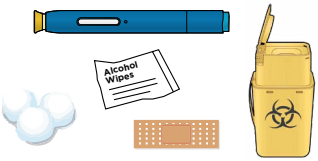
In all cases, call Amgen Medical Information on 0800 443 885. If required, you will be advised to contact your healthcare provider and use a new pre-filled pen.



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 SureClick pre-filled pen
- Alcohol wipes
- Cotton ball or gauze pad
- Adhesive bandage
- Sharps disposal container



D Prepare and clean your injection site.

You can use:

- Your thigh
- Stomach area (abdomen), except for a 5 cm (2-inch) area right around your belly button

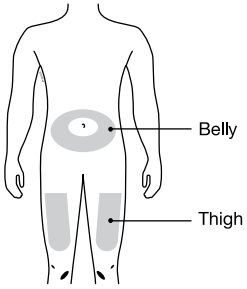
Clean your injection site with an alcohol wipe. Let your skin dry.

⦸ **Do not** touch this area again before injecting. Choose a different site each time you give yourself an injection.

- 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.

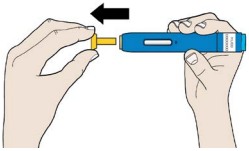
It is normal to see a drop of liquid at the end of the needle or yellow safety guard.

⦸ **Do not**

✘ Twist or bend the yellow cap.

✘ Put the yellow cap back onto the SureClick pre-filled pen.

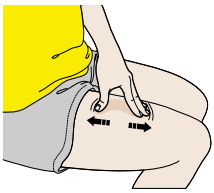
✘ Remove the yellow cap from the SureClick pre-filled pen until you are ready to inject.



❗ **IMPORTANT:** Throw the yellow cap into the sharps disposal container.

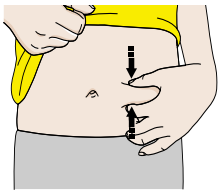
F Stretch or pinch your injection site to create a firm surface.

Stretch method



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

OR Pinch method

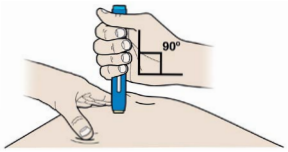


Pinch the skin firmly between your thumb and fingers, creating an area about 5 cm (2-inch) wide.

❗ **IMPORTANT:** Keep the skin stretched or pinched while injecting.

STEP 3: INJECT

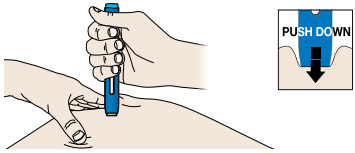
G Hold the stretch or pinch. With the yellow cap off, place the SureClick pre-filled pen on your skin at 90 degrees.



Make sure the window is visible to you.

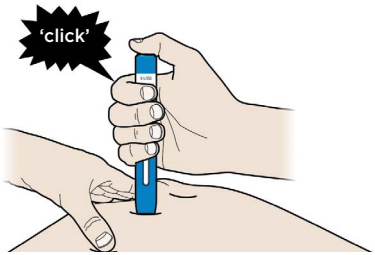
❗ **IMPORTANT: Do not touch the blue start button yet.**

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



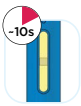
❗ **IMPORTANT:** You must push the yellow safety guard all the way down against your skin to unlock the activation mechanism but do not touch the blue start button until you are ready to inject.

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.

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.

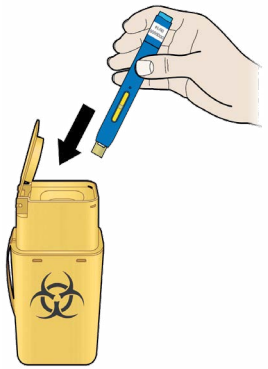
❗ **IMPORTANT:** When you remove the SureClick pre-filled pen, if the window has not turned yellow, or if it looks like the medicine is still injecting, this means you have not received a full dose. Call your healthcare provider immediately.

STEP 4: FINISH

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

- Put the used SureClick 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.

Do not
✘ Reuse the SureClick pre-filled pen.
✘ Recycle the SureClick 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.

If you do not have a sharps disposal container, you may use a household container that:

- Is made of a heavy-duty plastic
- Can be closed and has a tight-fitting, puncture-resistant lid, without sharp objects being able to come out
- Is upright and stable during use
- Is leak-resistant and is properly labelled to warn of hazardous waste inside the container.

L Examine the injection site.

If there is blood, press a cotton ball or gauze pad on your injection site. **Do not** rub the injection site.

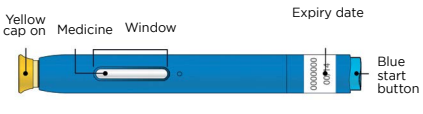
Apply an adhesive bandage if needed.

Possible injection site side effects[1]

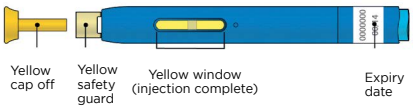
Reported common side effects include injection site reactions (redness, itching, pain or swelling).

Contact your healthcare provider or Amgen Medical Information on 0800 443 885 if any of these side effects worry you.

GUIDE TO PARTS



Before use



After use

These instructions are specific to the SureClick pre-filled pen. If you have been prescribed the AMGEVITA pre-filled syringe, please review the Instructions for Use included in your medication pack or view the instructional video at amgevita.co.nz.

SPECIAL INSTRUCTIONS FOR USE & HANDLING[1,2]

- AMGEVITA SureClick pre-filled pen is intended for one dose in one patient only.
- AMGEVITA SureClick pre-filled pen is intended for use under the guidance and supervision of a physician. Patients may self-inject AMGEVITA if proper training in injection technique has been received.
- For a more comfortable injection, leave the pre-filled pen at room temperature for 15 to 30 minutes before injecting.
- Avoid vigorous shaking of the AMGEVITA SureClick pre-filled pen.
- Do not use an AMGEVITA SureClick pre-filled pen if it has been dropped on a hard surface. Part of the AMGEVITA SureClick pre-filled pen may be broken even if you cannot see the break.
- The needle cover of the AMGEVITA SureClick pre-filled pen is made from dry natural rubber, which contains latex. Tell your healthcare provider if you are allergic to latex.

SPECIAL PRECAUTIONS FOR STORAGE[1]

- AMGEVITA SureClick pre-filled pen must be refrigerated at 2°C to 8°C. DO NOT FREEZE.
- Do not use if frozen, even if it has been thawed.
- Store in original carton until time of administration to protect from light.
- AMGEVITA SureClick pre-filled pen may be stored at room temperature (below 25°C) for a period of up to 14 days, with protection from light. AMGEVITA SureClick pre-filled pen should be discarded if not used within the 14-day period.
- Do not use AMGEVITA SureClick pre-filled pen after the expiry date.

Like all medicines, this medicine can cause side effects, although not everybody gets them. Most side effects are mild to moderate. However, some may be serious and require treatment. If you get any side effects, talk to your healthcare provider or pharmacist as soon as possible.[1]

For more information on AMGEVITA or to report a side effect involving AMGEVITA or product complaint contact Amgen Medical Information on 0800 443 885 or email: MEDINFO.JAPAC@amgen.com

IMPORTANT INFORMATION ABOUT AMGEVITA: AMGEVITA® is a prescription medicine containing adalimumab. AMGEVITA is available as single use pre-filled syringe(s) (containing 20 mg or 40 mg adalimumab) or single-use pre-filled pens (containing 40 mg adalimumab). AMGEVITA is a biosimilar medicine comparable to Humira®. *What AMGEVITA is used for.* AMGEVITA is used to reduce inflammation in patients with some inflammatory diseases, including rheumatoid arthritis, polyarticular juvenile idiopathic arthritis, enthesitis-related arthritis, psoriasis, psoriatic arthritis, ankylosing spondylitis, non-radiographic axial spondyloarthritis, Crohn's disease, ulcerative colitis, hidradenitis suppurativa, and uveitis. **AMGEVITA has risks and benefits.** *Do not use AMGEVITA if you have:* an allergy to any medicines containing adalimumab or any of the other ingredients in AMGEVITA; a severe infection; tuberculosis (known as TB); moderate-severe heart failure; or if using a medicine containing abatacept (Orencia®) or anakinra. *Before you use AMGEVITA tell your doctor if you have:* a current infection or a history of infections that keep coming back (including TB, hepatitis B, fungal or any other infection); any conditions that increase the risk of infections; had close contact with someone with TB, or Hepatitis B virus (HBV) or are a carrier of HBV; conditions that affect protective nerve layers, such as multiple sclerosis; blood disorders; low resistance to infections or diseases; any serious heart conditions or cancers; disorders that occur when the immune system attacks and destroys healthy cells, tissues, or organs by mistake; lung diseases that make breathing difficult; inflammation of the middle layer of the eye (uveitis); kidney or liver problems; psoriasis (a type of skin disease) and have undergone phototherapy; or if you have any allergies. Your risk of getting serious infections or certain kinds of cancer may increase if you take AMGEVITA. In rare cases, these infections may be life-threatening. Tell your doctor if you are pregnant or plan to become pregnant, or if you are breastfeeding or plan to. *Tell your doctor immediately or go to your nearest hospital if you develop symptoms*: of an allergic reaction, such as chest tightness, shortness of breath or difficulty breathing, swelling of the face, lips or tongue, or a rash; heart problems, such as shortness of breath with exertion or lying down, swollen feet; or signs of blood disorders, such as a persistent fever, bruising, bleeding easily, paleness. Tell your doctor straight away if: symptoms of TB or any other infection appear during treatment (such as fever, persistent cough, weight loss, listlessness or lack of energy, skin sores, problems with your teeth and gums, burning when you pass urine, etc); you develop cancer, skin lesions (new skin spots or sores), or if existing lesions change appearance; nervous system disorders (such as numbness, or tingling, arm or leg weakness, double vision). Tell your doctor straight away if you become pregnant while using AMGEVITA. If you use AMGEVITA during pregnancy, your baby may have a higher risk of getting an infection. It is important that you tell your baby's doctors and other healthcare professionals about your AMGEVITA use during your pregnancy before the baby receives any vaccine. *Tell your doctor and other healthcare professionals:* if you are taking any other medicines, including any that you get without a prescription; if you are going to have surgery, or if you are scheduled for any vaccines. Patients taking AMGEVITA should not receive live vaccines. Tell all doctors, dentists, and pharmacists who are treating you that you are using AMGEVITA. *Common Side Effects:* Tell your doctor if you experience any side effects that make you feel unwell. The most common side effects of this medicine are injection site reactions (e.g. pain, swelling, redness); respiratory tract infections; ear or eye pain, inflammation of the eye or eye lid; mouth ulcers, pain or 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; muscle weakness or numbness; tummy pain, nausea, vomiting, reflux or heartburn; chest pain; rash, itching; finger or toe nail problems; hair loss; tiredness; muscle, joint or bone pain; bleeding or bruising more easily; depression or anxiety; increased heart rate; and infections caused by viruses, bacteria or fungi. Your doctor might also tell you about abnormal laboratory test results, such as reduced blood cell counts for example. **Ask your doctor if AMGEVITA is right for you. Use strictly as directed. Please read the safety information in the AMGEVITA Consumer Medicines Information (CMI), available at** www.medsafe.govt.nz/Consumers/cmi/a/amgevita.pdf **or telephone 0800 443 885 (free call).** If you have any questions about using AMGEVITA, or if symptoms continue, or you have side effects, speak to your healthcare professional.

AMGEVITA is fully funded for most of the above conditions (under Special Authority) except for enthesitis-related arthritis and non-radiographic axial spondyloarthritis. Normal pharmacy prescription and doctor's charges will apply. Amgen (New Zealand) Limited, Auckland, New Zealand. Telephone: 0800 443 885. E-mail medinfo.JAPAC@amgen.com. V1. TAPS MR797.

References: 1. AMGEVITA® Consumer Medicine Information.
2. AMGEVITA® Approved Data Sheet. **3.** AMGEVITA® SureClick Instructions for use 9 April 2021. Available at: https://www.amgevita.co.nz/-/media/Themes/Amgen/Amgevita-nz/Amgevita-nz/pdf/amgevita_nz_%20pf_pen_ifu (Accessed November 2022).

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Telephone: 0800 443 885 | Email: medinfo.JAPAC@amgen.com
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AMGEN®

AMGEVITA® (adalimumab)