AMGEVITA® (adalimumab)

WHAT'S BEHIND AMGEVITA® MAKES THE DIFFERENCE

Introduction to AMGEVITA

AMGEVITA, the adalimumab biosimilar from Amgen, is available on the Pharmaceutical Schedule in New Zealand[1]

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

AMGEN®

TRIED AND TESTED

AMGEVITA demonstrated similar safety, efficacy, and immunogenicity to Humira® (adalimumab) in pharmacokinetic and clinical trials that included over 800 patients.[2-5]

AMGEVITA is registered in New Zealand for the same indications as Humira®:[2,6]

- Rheumatoid arthritis
- Juvenile idiopathic arthritis
  - Polyarticular juvenile idiopathic arthritis
  - Enthesitis-related arthritis
- Psoriatic arthritis
- Ankylosing spondylitis
- Non-radiographic axial spondyloarthritis
- Crohn's disease in children (≥ 6 years) and adults
- Ulcerative colitis in children (≥ 5 years) and adults
- Psoriasis in children (≥ 4 years) and adults
- Hidradenitis suppurativa in adolescents (≥ 12 years) and adults
- Uveitis
- Paediatric uveitis (≥ 2 years)

SPECIAL AUTHORITY CRITERIA

AMGEVITA is available on the Pharmaceutical Schedule and the Special Authority criteria introduced the following changes to improve access to treatment for all indications:[1]

- Removal of dosing restrictions
- Extension of Special Authority renewal periods to 2 years
- Ability for any relevant practitioner to apply for Special Authority renewals
- Removal of the requirement for Special Authority renewal applications for some conditions

These access widenings are specific to the AMGEVITA brand of adalimumab.

Special Authority criteria and Hospital Restrictions apply.
For a full list of AMGEVITA Special Authority criteria, you can visit the Pharmac website.

PROVEN DEVICE

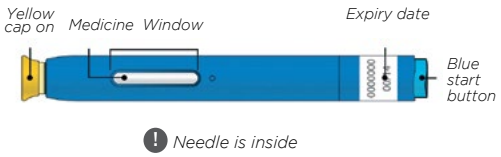
AMGEVITA is delivered with the SureClick® pre-filled pen, a device that has been registered for use with other medicines for over 15 years.[7]

AMGEVITA is a citrate-free formulation of adalimumab. This means that some patients may find it less painful to inject, since injectable medicines that contain citrate may cause 'stinging'.[8]

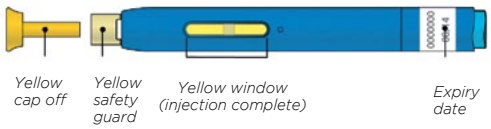
AMGEVITA PRODUCT DETAILS COMPARED TO REFERENCE PRODUCT[2,6]

	AMGEVITA	Humira®
Buffer	Citrate-free	Citrate & citrate-free
Storage	2-8°C, protect from light	2-8°C, protect from light
Room temperature storage (if necessary)	14 days <25°C	14 days <25°C
Shelf life	3 years	2 years
Presentations	• 40 mg pre-filled pen • 20 mg & 40 mg pre-filled syringe	• 40 mg & 80 mg pre-filled pen • 20 mg, 40 mg & 80 mg pre-filled syringe

GUIDE TO PARTS



Before use



After use

FOR MORE INFORMATION ON AMGEVITA OR THE AMGEN BIOSIMILARS PORTFOLIO, OR TO REPORT AN ADVERSE EVENT OR PRODUCT COMPLAINT INVOLVING AMGEVITA, PLEASE CONTACT AMGEN MEDICAL INFORMATION ON **0800 443 885** OR EMAIL: **MEDINFO.JAPAC@AMGEN.COM**

PHARMAC Pharmaceutical Schedule: Please refer to the adalimumab Special Authority for AMGEVITA® (adalimumab) indications that are fully subsidised. AMGEVITA® is not funded for enthesitis-related arthritis or non-radiographic axial spondyloarthritis.

Important note: Consult full AMGEVITA data sheet at www.medsafe.govt.nz before prescribing.

AMGEVITA® (adalimumab) is a prescription medicine containing 20 mg/0.4 mL & 40 mg/0.8 mL Solution for injection. Indications: Ankylosing Spondylitis; Crohn's Disease; Enthesitis-Related Arthritis; Hidradenitis Suppurativa; Non-radiographic Axial Spondyloarthritis; Polyarticular Juvenile Idiopathic Arthritis; Psoriasis; Psoriatic Arthritis; Rheumatoid Arthritis; Ulcerative colitis; Uveitis. **Presentations:** adalimumab 20 mg/0.4mL pre-filled syringe; adalimumab 40 mg/0.8 mL pre-filled syringes/pen. **Contraindications:** hypersensitivity to adalimumab or excipients; severe infections; active tuberculosis (TB); moderate to severe heart failure (NYHA class III/IV); concurrent anakinra administration. **Warnings and precautions:** Serious or opportunistic infections; congestive heart failure (CHF); hepatitis B; TB; neurologic events; hypersensitivity reactions; haematologic events; immunosuppression; live vaccines; malignancies; autoimmune processes; concurrent administration of biologic DMARDS or TNF-antagonists; psoriasis - use with systemic agents/phototherapy; surgery. Removable cap of pre-filled pen contains natural rubber (a derivative of latex). Pregnancy. Lactation. **Adverse reactions:** Very common: injection site reactions, respiratory tract infections; leucopenia; anaemia; headache; abdominal pain, nausea; vomiting; musculoskeletal pain; elevated lipids; elevated liver enzymes; and rash. Common: sepsis; other infections; benign neoplasm; skin cancer excluding melanoma; thrombocytopenia; leucocytosis; hypersensitivity; allergies; hypokalaemia; uric acid increased; blood sodium abnormal; hypocalcaemia; hyperglycaemia; hypophosphatemia; dehydration; mood alterations; anxiety; insomnia; paraesthesias; migraine; nerve root compression; visual impairment; conjunctivitis; blepharitis; eye swelling; vertigo; tachycardia; hypertension; flushing; haematoma; cough; asthma; dyspnoea; Gastrointestinal haemorrhage; dyspepsia; gastroesophageal reflux disease; sicca syndrome; cholecystitis & cholelithiasis; bilirubin increased; hepatic steatosis; pruritus; urticaria; bruising; dermatitis; onychoclasis; hyperhidrosis; muscle spasms, blood creatine phosphokinase increased; haematuria; renal impairment; chest pain; oedema; coagulation & bleeding disorders; activated partial thromboplastin time (APTT) prolonged; positive autoantibody test; blood lactate dehydrogenase (LDH) increased; and impaired healing. Serious (rare): fatal infections, including TB or invasive opportunistic infections. **Dosage:** See full data sheet. **Method of administration:** subcutaneous injection. **Packs:** 20 mg packs of 1; 40 mg packs of 2. AMGEVITA® is a registered trademark of Amgen New Zealand Limited, Auckland. Phone 0800 443 885. Version 1.

References: 1. Pharmac. Special Authority Criteria SA2178 – Adalimumab (Amgevita). Available at: https://schedule.pharmac.govt.nz/2024/03/01/SA2178.pdf (Accessed March 2024). **2.** AMGEVITA® Data Sheet. **3.** Cohen SB, *et al. Ann Rheum Dis* 2017;76:1679-1687. **4.** Papp K, *et al. J Am Acad Dermatol* 2017;76(6):1093-1102. **5.** Cohen SB, *et al. Arth Res Ther* 2019;21(1):84. **6.** Humira® Data Sheet **7.** Australian Register of Therapeutic Goods. Available at www.tga.gov.au/australian-register-therapeutic-goods. Accessed 4 March 2021. **8.** Pharmac. Decision to widen access to adalimumab and award Principal Supply. 17 November 2021. Available at: https://pharmac.govt.nz/news-and-resources/consultations-and-decisions/2021-11-17-decision-to-widen-access-to-adalimumab-and-award-principal-supply (Accessed March 2024).

Humira® is a registered trademark of AbbVie Biotechnology Ltd.

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Scan QR code for AMGEVITA Data Sheet

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