AMGEVITA® (adalimumab)

WHAT'S BEHIND AMGEVITA® *MAKES THE DIFFERENCE*

We are pleased to announce that AMGEVITA, the adalimumab biosimilar from Amgen, is now available in New Zealand

From 1 March 2022, AMGEVITA will be available on the Pharmaceutical Schedule. Special Authority criteria and hospital restrictions will apply. **For full criteria visit https://pharmac.govt.nz/assets/2021-11-Amgevita-Special-Authority.pdf**[1]

Amgen is recognised worldwide as a leader in manufacturing complex biologic therapies; we are committed to excellence in manufacturing, with stringent controls to maintain product quality and ongoing supply.[2]

YOU CAN PRESCRIBE AMGEVITA WITH CONFIDENCE:

Track record

AMGEVITA is backed by nearly four decades of experience in biologics manufacture and a history of reliable product supply.[3]

Tried and tested

Similar safety, efficacy and immunogenicity to Humira® proven in multiple trials# of AMGEVITA in over 800 patients.[4-7]

#analytical, non-clinical, pharmacokinetic and clinical.

Proven device

AMGEVITA is citrate free and delivered with the SureClick® pre-filled pen, a device that has been registered for use with other medicines for over 14 years.[8]

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'.[9]

FOR MORE INFORMATION ON AMGEVITA OR THE AMGEN BIOSIMILARS PORTFOLIO PLEASE CONTACT AMGEN MEDICAL INFORMATION ON **0800 443 885** OR EMAIL: **MEDINFO.JAPAC@AMGEN.COM**

For more information on AMGEVITA 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: Effective 01 March 2022, 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. AMGEVITA access criteria. Pharmac.govt.nz/assets/2021-11-Amgevita-Special-Authority.pdf. **2.** Amgen Biosimilars. Expertise - Quality Assurance. Available at: https://www.amgenbiosimilars.com/expertise/quality-assurance. Accessed December 2021. **3.** Amgen. Data on file. **4.** AMGEVITA® Approved Data Sheet available at medsafe.govt.nz. **5.** Cohen SB et al. Ann Rheum Dis 2017;76:1679-1687. **6.** Papp K et al. J Am Acad Dermatol; 2017;76:1093-1102. **7.** Cohen SB et al. Arth Res Ther 2019;21:84. **8.** Australian Register of Therapeutic Goods. Available at www.tga.gov.au/australian-register-therapeutic-goods. Accessed 4 March 2021. **9.** PHARMAC Adalimumab Changes: What patients need to know. https://pharmac.govt.nz/medicine-funding-and-supply/medicine-notices/adalimumab/adalimumab-changes-what-patients-need-to-know/ Accessed 10 January 2022.

Humira® is a registered trademark of AbbVie Biotechnology Ltd.

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