WHAT'S BEHIND AMGEVITA®
MAKES THE DIFFERENCE

20 January 2022

Amgen New Zealand are pleased to announce that AMGEVITA, the adalimumab biosimilar from Amgen, is now available in New Zealand and will be listed on the Pharmaceutical Schedule from ***1 March 2022.***[1]

The Special Authority criteria for AMGEVITA will include:

- All currently funded uses for adalimumab (Humira®) 20 mg and 40 mg products
- Widened access to include specific indication and prescribing criteria changes
- Availability for several new indications including first-line treatment of ulcerative colitis

For a full list of ***AMGEVITA Special Authority criteria,*** you can visit pharmac.govt.nz[2]

Enclosed with this letter is an information leaflet, which will provide further detail on the background and support that is available to you and your patients for AMGEVITA.

In February, we will send you an information pack to help you learn more about AMGEVITA in preparation for starting your patients on treatment. We would suggest to plan some time with your team in late February to familiarise yourselves with the AMGEVITA materials, which will include:

- Reusable SureClick® demonstration pen
- *Introduction to AMGEVITA* for Healthcare Professionals booklet
- *AMGEVITA Patient Information* booklet, including self-injection instructions
- Details of the AMGEVITA support available for you and your patients

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. Pharmac consultation decision 17 November 2021. Available at pharmac.govt.nz/news-and-resources/consultations-and-decisions **2.** AMGEVITA access criteria. Pharmac.govt.nz/assets/2021-11-Amgevita-Special-Authority.pdf. Accessed 23 Dec 2021

Humira® is a registered trademark of AbbVie Biotechnology Ltd.

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AMGEVITA® (adalimumab)