AMGEVITA® (adalimumab)

SUPPORT FOR YOU, YOUR TEAM AND YOUR PATIENTS WHEN STARTING AMGEVITA®

We are pleased to advise that AMGEVITA, the adalimumab biosimilar from Amgen, will be available on the Pharmaceutical Schedule in New Zealand from 1 March 2022.[1]

All patients who are new to treatment with adalimumab will need to start treatment with AMGEVITA, as per the relevant Special Authority initial criteria.

The criteria includes:

- 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

A list of AMGEVITA Special Authority criteria can be found later in this announcement or by visiting **pharmac.govt.nz**

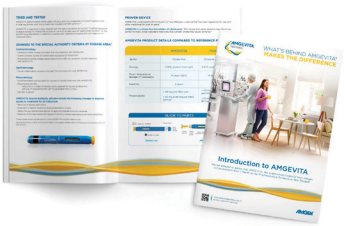
Resources available to familiarise your team with AMGEVITA

To help you prepare for starting patients on treatment, we have included the following resources in this pack:

Reusable SureClick® Demonstration Pen

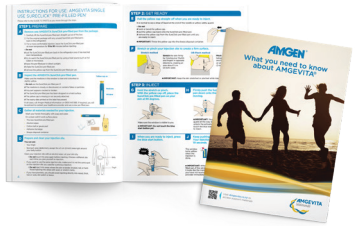
To assist your team with understanding the injection process prior to onboarding patients

Introduction to AMGEVITA



A useful booklet for Healthcare Professionals

AMGEVITA Patient Information



Step-by-step instruction booklet for how to self-inject with the SureClick pre-filled pen

AMGEVITA Patient Support Materials

Alert cards, contact tear-off pads and reminder leaflets for adults and children

Further resources for patients and HCPs are available online at amgevita.co.nz
These include FAQs and videos with instructions on how to inject AMGEVITA.

Register at *amgevitahcp.co.nz* to view healthcare professional materials

The timeline for patients to begin using and switching over to the newly funded adalimumab (AMGEVITA) has been published at pharmac.govt.nz.[3]

AMGEVITA Important Dates

From 1 March 2022

All people currently using adalimumab will be automatically issued with a Special Authority number for AMGEVITA. You should ensure that any prescription for adalimumab clearly specifies the brand of adalimumab that should be dispensed.

Both AMGEVITA and Humira® will be funded for existing patients and uses. Patients under your care who are using Humira® should be changed to AMGEVITA.* Only AMGEVITA will be funded for new patients and uses (widened access).[3]

From 1 October 2022

Only AMGEVITA will be funded for all uses (current and new).*[3]

*There are some exceptions; please refer to pharmac.govt.nz for full details.

From 1 March 2022, access to AMGEVITA will be subject to Special Authority criteria and hospital restrictions

The Special Authority criteria for AMGEVITA includes all currently funded uses for adalimumab (Humira®) 20 mg and 40 mg presentations.

Changes* to the Special Authority criteria by disease area:[1]

Gastroenterology

- Ulcerative colitis: access to funded first-line treatment with AMGEVITA
- Crohn's disease: access to funded dose escalation of AMGEVITA
- Inflammatory bowel disease-associated arthritis (IBD-A): access to funded treatment with AMGEVITA

Ophthalmology

- Ocular inflammation: access to funded first-line treatment with AMGEVITA

Rheumatology

- Rheumatoid arthritis:
  - reduction in number of swollen joints required for access to treatment
  - removal of requirement for CRP to be greater than 15 mg/L
- See IBD-A above

*These are not a complete list of the changes. Refer to pharmac.govt.nz for the full details.

AMGEVITA Special Authority will also include the following changes to improve access to treatment for all indications

- 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. Please refer to Pharmaceutical Schedule for full information.

AMGEVITA Support Nurse

Your patients can access information about AMGEVITA and how to administer the SureClick pre-filled pen device or pre-filled syringe via our patient portal at amgevita.co.nz

If your patients have further questions or need assistance with the injection, our support nurse is available to help.

Contact: 0800 AMGEVITA (264 384)
Email: amgevita.nz@greencrosshealth.co.nz
Business Hours: 9am to 5pm, Monday - Friday
Outside Business Hours: Patients can leave a voicemail message or email and our nurse will return the message as soon as possible.

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. 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. **3.** Pharmac Adalimumab (Amgevita): Information for health care professionals. https://pharmac.govt.nz/medicine-funding-and-supply/medicine-notices/adalimumab/adalimumab-amgevita-information-for-health-care-professionals/ Accessed 10 January 2022.

Humira® is a registered trademark of AbbVie Biotechnology Ltd.

Amgen (New Zealand) Limited, Level 22, PwC Tower, 15 Customs Street West, Auckland 1010.
Telephone: 0800 443 885 | Email: medinfo.JAPAC@amgen.com
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Scan QR code for AMGEVITA Data Sheet

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