AMGEVITA® (adalimumab)

# WHAT'S BEHIND AMGEVITA® MAKES THE DIFFERENCE

## AMGEVITA, the new adalimumab biosimilar from Amgen, is now available on the PBS.[1]

Amgen Australia are pleased to advise you that from 1st April 2021 AMGEVITA is available on the Pharmaceucial Benefits Scheme (PBS). The PBS Authority listings for AMGEVITA include all indications as PBS-listed for Humira® (adalimumab) 20 mg and 40 mg presentations.[1]

### 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.[2,3]

#### Tried and tested

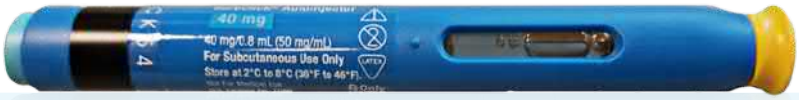
Similar safety, efficacy and immunogenicity to Humira® proven in multiple trials# of AMGEVITA in over 800 patients.[4-7]

#analytical, non-clinical, pharmacokinetic and clinical[4]

#### Proven device

AMGEVITA is delivered with the SureClick® pre-filled pen, a device used by patients in Australia for over 14 years.*[8]

*Aranesp® (darbepoetin alfa) SureClick pre-filled pen has been registered in Australia since 2006.




SCAN QR CODE FOR FURTHER INFORMATION ON THEPBS LISTINGS FOR AMGEVITA OR TO REQUEST AN INFORMATION PACK - INCLUDING A SURECLICK PLACEBO DEMONSTRATION DEVICE

## 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 Australia with the same indications as Humira.[2] The PBS Authority listings for AMGEVITA include all indications, as listed for Humira® 20 mg and 40 mg presentations.[1]

| Indication†[2] | AMGEVITA | Humira | AMGEVITA PBS Listing*[1] |
|---|---|---|---|
| Rheumatoid arthritis | ✓ | ✓ | ✓ |
| Juvenile idiopathic arthritis | ✓ | ✓ | ✓ |
| Psoriatic arthritis | ✓ | ✓ | ✓ |
| Ankylosing spondylitis | ✓ | ✓ | ✓ |
| Crohns disesase in adults and children ≥ 6 years | ✓ | ✓ | ✓ |
| Ulcerative colitis | ✓ | ✓ | ✓ |
| Psoriais in adults and children ≥ 4 years | ✓ | ✓ | ✓ |
| Hidradenitis suppurativa in adults & adolescents ≥ 12 years | ✓ | ✓ | ✓ |
| Uveitis | ✓ | ✓ | ✓ |

*Authority required. Please refer to Schedule of Pharmaceutical benefits for full information.
†Refer to Approved Product Information for full details.

## AMGEVITA product details compared to reference product[2,6,7]

| | AMGEVITA | Humira® |
|---|---|---|
| Buffer | Non-citrate | Citrate & non-citrate |
| 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 | 36 months | 24 months |
| Presentations | • 40 mg pre-filled pen<br>• 20 mg & 40 mg pre-filled syringe | • 40 mg & 80 mg pre-filled pen<br>• 20 mg, 40 mg & 80 mg pre-filled syringe |

## PROVEN DEVICE

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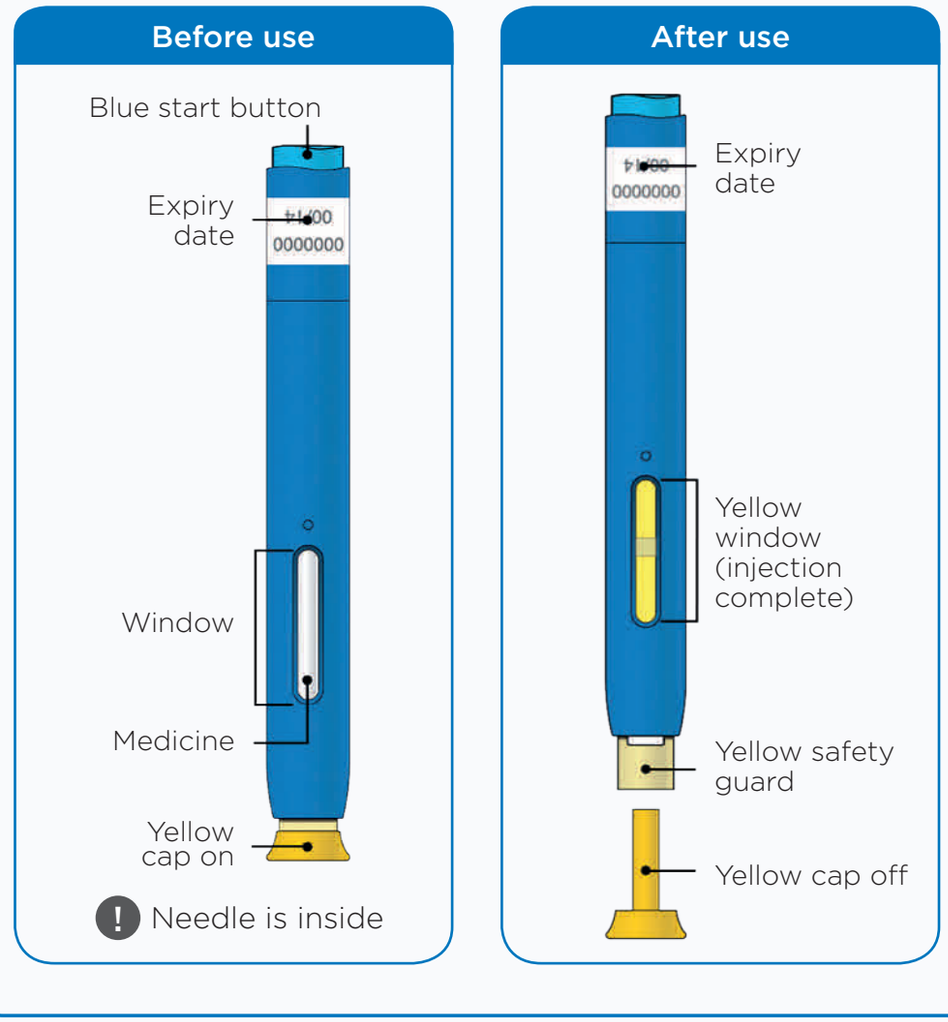
## GUIDE TO PARTS




FOR MORE INFORMATION ON AMGEVITA OR THE AMGEN BIOSIMILARS PORTFOLIO PLEASE CONTACT AMGEN MEDICAL INFORMATION ON **1800 803 638** OR EMAIL: **MEDINFO.JAPAC@AMGEN.COM**

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**PBS Information:** Authority required. Refer to PBS Schedule for full authority information.

Please review the Approved Product Information for AMGEVITA® before prescribing. Product Information is available from www.amgen.com.au/Amgevita.PI

**MINIMUM PRODUCT INFORMATION. AMGEVITA (adalimumab). INDICATIONS:** Rheumatoid Arthritis (RA) in adults: Monotherapy or combination with methotrexate (MTX) in moderate to severe RA, including recently diagnosed MTX-naïve RA patients. Paediatric Polyarticular Juvenile Idiopathic Arthritis (pJIA): In combination with MTX for moderately to severe pJIA in patients ≥ 2 years of age where response to previous DMARDS has been inadequate, or as monotherapy in case of intolerance to MTX or when continued treatment with MTX is inappropriate. Enthesitis-Related Arthritis (ERA): In children who have had an inadequate response to, or who are intolerant to, conventional therapy. Psoriatic Arthritis (PsA) in adults: Moderate to severe PsA in patients where response to previous DMARDS has been inadequate. Ankylosing Spondylitis (AS) in adults: Reducing signs and symptoms in active AS. Crohn's Disease (CD) in children ≥ 6 years of age & adults: Moderate to severe CD. Induce and maintain clinical remission in patients who have had an inadequate response to conventional therapies or, who have lost response to/are intolerant of infliximab. Ulcerative colitis (UC) in adults: Moderate to severe UC in patients who have had an inadequate response to conventional therapy/are intolerant to or have medical contraindications for such therapies. Psoriasis (Ps) in children ≥ 4 years of age, adolescents & adults: Severe chronic plaque Ps in children & adolescents who have had an inadequate response to or are inappropriate for topical and photo therapies; moderate to severe Ps in adult patients who are candidates for systemic or photo therapies. Hidradenitis Suppurativa (HS) in adults and adolescents (from 12 years of age): Moderate to severe HS (acne inversa) in patients with an inadequate response to conventional therapy. Non-infectious intermediate, posterior and pan-uveitis (Uv) in adults: Treatment of patients who have had an inadequate response to/cannot take corticosteroids. **CONTRAINDICATIONS:** Severe infections, sepsis, active TB, other opportunistic infections; concurrent anakinra; moderate to severe heart failure (NYHA class III/IV); hypersensitivity to adalimumab or ingredients. **PRECAUTIONS:** Serious bacterial, mycobacterial, invasive fungal, viral, parasitic, or other opportunistic infections; hepatitis B; tuberculosis; neurological events; hypersensitivity reactions; latex; haematologic events; immunosuppression; live vaccines; new or worsening congestive heart failure (CHF); malignancies; autoimmune processes; concurrent administration of biologic DMARDS or TNF-antagonists; use in psoriasis with systemic agents or phototherapy; surgery; renal impairment; hepatic impairment; elderly use; paediatric use; increased liver enzymes; effects on fertility; pregnancy category C; lactation. **INTERACTIONS:** Anakinra; abatacept. **ADVERSE EFFECTS: Very common:** Respiratory tract infections; leucopenia; anemia; lipids increased; headache; abdominal pain, nausea; vomiting; liver enzymes elevated; rash; musculoskeletal pain; injection site reaction. **Common:** Systemic infections; intestinal infections; skin and soft tissue infections; ear infections, oral infections; reproductive tract infections; urinary tract infections; fungal infections; tinea pedis; joint infections; gastroenteritis; pharyngitis; tonsillitis; cystitis; benign neoplasm; non-melanoma skin cancers; injection site swelling; pruritus; urticaria; dermatitis; onychoclasis; hyperhydrosis; skin papilloma; diffuse alopecia; psoriasis; psoriatic arthropathy; bruising; thrombocytopenia; leukocytosis; hypersensitivity; allergies; hypokalemia; uric acid increased; abnormal serum sodium; hypocalcemia; hyperglycemia; hypophosphatemia; hypercholesterolemia; dehydration; mood alterations; anxiety; depression; insomnia; paraesthesias; migraine; nerve root compression; oropharyngeal pain; visual impairment; conjunctivitis; blepharitis; eye swelling; vertigo; tachycardia; hypertension; flushing; haematoma; cough; upper respiratory tract infections; sinusitis; rhinitis; rhinorrhoea; bronchitis; toothache; dental caries; pulpitis dental; asthma; dyspnoea; decreased appetite; GI haemorrhage; diarrhoea; dyspepsia; gastroesophageal reflux disease; sicca syndrome; muscle spasms; ligament strain; back pain; musculoskeletal pain; spinal pain; arthralgia; myalgia; pain in extremity; rheumatoid arthritis; blood CPK increased; renal impairment; haematuria; chest pain; oedema; excoriation; intertrigo; thermal burn; coagulation and bleeding disorders; autoantibody test positive; blood lactate dehydrogenase increased; impaired healing. For others, see full PI. **DOSAGE AND ADMINISTRATION: RA:** 40 mg sc fortnightly; 40 mg sc weekly or 80 mg sc fortnightly in some patients. **pJIA, ERA:** Paediatrics ≥ 2 years: 10 kg to <30 kg: 20 mg sc fortnightly; ≥30 kg: 40 mg sc fortnightly **PsA:** 40 mg sc fortnightly. **AS:** 40 mg sc fortnightly. **CD:** Paediatrics 6-17 years (moderate and severe): <40 kg - Induction: 80 mg sc (2 x 40 mg injections on Day 0), and 40 mg sc on Day 14. Maintenance: 20 mg sc starting on Day 28 and continuing fortnightly. Paediatrics ≥ 40kg – Induction: 160 mg sc (4 x 40 mg on Day 0 OR 2 x 40 mg on Day 0 and Day 1); 80 mg sc (2 x 40 mg) on Day 14. Maintenance: 40 mg sc starting on Day 28 and continuing fortnightly. Adult - Induction: 160 mg sc (4 x 40 mg on Day 0 OR 2 x 40 mg on Day 0 and 2 x 40 mg on Day 1); 80 mg sc (2 x 40 mg) on Day 14. Maintenance: 40 mg sc starting on Day 28 and continuing fortnightly. **Ps:** Paediatrics 4 to 17 years: < 40 kg: 20 mg sc fortnightly; ≥40 kg: 40 mg sc fortnightly. Adults: 80 mg sc (2 x 40 mg) on Day 1; 40 mg sc fortnightly, starting Day 8. **UC:** Adult induction: 160 mg sc (4 x 40 mg injections on Day 0 OR 2 x 40 mg injections on Days 0 and 1); 80 mg sc on Day 14 (2 x 40 mg). Maintenance: 40 mg sc on Day 28 and continuing fortnightly. **HS:** Adults: 160 mg sc (4 x 40 mg on Day 1 OR 2 x 40 mg on Day 0 and 2 x 40 mg on Day 1); 80 mg sc (2 x 40 mg) on Day 15; 40 mg sc starting on Day 29 and continuing fortnightly. Adolescents: 80 mg sc (2 x 40 mg) on Day 1; 40 mg sc on Day 8; 40 mg sc on day 22 and continuing fortnightly (maintenance dose). **Uv:** 80 mg sc (2 x 40 mg injections) on Day 0; 40 mg sc on Day 7 and continuing fortnightly. **PRESENTATIONS:** 20 mg and 40 mg pre-filled syringe; 40 mg pre-filled pen.

For more information on AMGEVITA or to report an adverse event or product complaint involving AMGEVITA, please contact Amgen Medical Information on 1800 803 638.

**References: 1.** Schedule of Pharmaceutical Benefits, April 1, 2021. Available at: www.pbs.gov.au. **2.** Amgen Biosimilars. Heritage - Deep Experience. Available at: https://www.amgenbiosimilars.com/heritage/deep-experience Accessed 4 March 2021. **3.** Amgen. Data on file, 2019. **4.** AMGEVITA® Approved Product Information. **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.

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