A GUIDE TO AMGEVITA®: AN ADALIMUMAB BY AMGEN

PrAMGEVITA® adalimumab injection

Please see the Product Monograph for complete dosing and administration information.

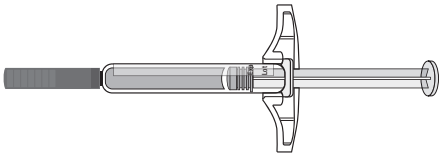
See indications and dosing details on the next page.

AMGEVITA® DOSES AND FORMATS AVAILABLE FOR YOUR PRACTICE.[1]

AMGEVITA® 40 mg IS AVAILABLE IN A SINGLE-USE PREFILLED SURECLICK® AUTOINJECTOR

BLUE START BUTTON | INSPECTION WINDOW | YELLOW CAP

AMGEVITA® 20 mg AND 40 mg ARE AVAILABLE IN A PREFILLED SYRINGE



- All AMGEVITA® formulations are **100% citrate-free.***,†
- PFS Prefilled syringes are **latex-free.***
- Direct your patients to **www.amgevita.ca**‡ for a video on how to inject with a SureClick® autoinjector.

Formats	DIN	Barcode
40 mg AMGEVITA® SureClick® autoinjector	02459302	6 27061 00011 6
40 mg prefilled syringe	02459299	6 27061 00012 3
20 mg prefilled syringe	02459310	6 27061 00015 4

STORAGE IS THE SAME FOR BOTH FORMATS

Must be refrigerated at 2 °C to 8 °C. DO NOT FREEZE. Do not use if frozen even if it has been thawed. Do not store in extreme heat or cold.

- If needed, for example when travelling, AMGEVITA® may be stored at room temperature (up to 25 °C) for a **maximum of 14 days** (with protection from light). Discard if not used within the 14-day period.

Please consult the Product Monograph for complete information and administration instructions.

Indications have been granted on the basis of similarity between AMGEVITA® and the reference biologic drug HUMIRA®. AMGEVITA® (adalimumab) is indicated for the treatment of adult patients with chronic moderate to severe plaque psoriasis (PsO) who are candidates for systemic therapy. For patients with chronic moderate PsO, AMGEVITA® should be used after phototherapy has been shown to be ineffective or inappropriate.

See reverse for full list of indications.

VISIT AMGEVITA.CA‡

Scan this QR code to go directly to the website.

DIN: drug identification number
*Clinical significance is unknown.
†Non-medicinal ingredients in AMGEVITA® include glacial acetic acid, polysorbate 80, sodium hydroxide, sucrose, and water for injection.
‡The amgevita.ca landing page is open to the general public.

Amgen Entrust™ Patient Support Services provide support for you and your patients every step of the way.

Call: 1-877-936-2735

Email: amgevita@oneenliven.ca

Patients and/or caregivers **need to be trained to inject** with the AMGEVITA® SureClick® autoinjector or prefilled syringe.

Amgen Entrust™ Patient Support Services offer injection training, patient assistance, and personalized support for healthcare professionals.

AMGEN Entrust™ Enliven®

AMGEVITA® HAS ALL THE SAME INDICATIONS AS ORIGINATOR ADALIMUMAB (HUMIRA®)[1,2]

Indications

Adult Crohn's disease: reducing signs and symptoms and inducing and maintaining clinical remission in adult patients with moderately to severely active Crohn's disease (CD) who have had an inadequate response to conventional therapy, including corticosteroids and/or immunosuppressants. AMGEVITA® is indicated for reducing signs and symptoms and inducing clinical remission in these patients if they have also lost response to or are intolerant to infliximab. **Adult ulcerative colitis:** treatment of adult patients with moderately to severely active ulcerative colitis (UC) who have had an inadequate response to conventional therapy including corticosteroids, and/or azathioprine, or 6-mercaptopurine (6-MP) or who are intolerant to such therapies. The efficacy of AMGEVITA® in patients who have lost response to or were intolerant to tumour necrosis factor (TNF)-blockers has not been established. **Pediatric Crohn's disease:** reducing signs and symptoms and inducing and maintaining clinical remission in pediatric patients 13 to 17 years of age weighing ≥ 40 kg with severely active CD and/or who have had an inadequate response or were intolerant to conventional therapy (a corticosteroid and/or aminosalicylate and/or an immunosuppressant) and/or a TNF-alpha antagonist. **Pediatric ulcerative colitis:** inducing and maintaining clinical remission in pediatric patients 5 years of age and older with moderately to severely active UC who have had an inadequate response to conventional therapy including corticosteroids and/or azathioprine or 6-MP or who are intolerant to such therapies.

Rheumatoid arthritis: reducing the signs and symptoms, inducing major clinical response and clinical remission, inhibiting the progression of structural damage and improving physical function in adult patients with moderately to severely active rheumatoid arthritis (RA). AMGEVITA® can be used alone or in combination with methotrexate (MTX) or other disease-modifying anti-rheumatic drugs (DMARDs). When used as first-line treatment in recently diagnosed patients who have not been previously treated with MTX, AMGEVITA® should be given in combination with MTX. AMGEVITA® can be given as monotherapy in case of intolerance to MTX or when treatment with MTX is contraindicated. **Psoriatic arthritis:** reducing the signs and symptoms of active arthritis and inhibiting the progression of structural damage and improving the physical function in adult psoriatic arthritis (PsA) patients. AMGEVITA® can be used in combination with MTX in patients who do not respond adequately to MTX alone. **Ankylosing spondylitis:** reducing signs and symptoms in adult patients with active ankylosing spondylitis (AS) who have had an inadequate response to conventional therapy. **Polyarticular juvenile idiopathic arthritis:** in combination with MTX, reducing signs and symptoms of moderately to severely active polyarticular juvenile idiopathic arthritis (JIA) in patients 2 years of age and older who have had an inadequate response to one or more DMARDs. AMGEVITA® can be used as monotherapy in case of intolerance to MTX or when continued treatment with MTX is not appropriate. Adalimumab has not been studied in pediatric patients with polyarticular JIA aged less than 2 years.

Plaque psoriasis: treatment of adult patients with chronic moderate to severe plaque psoriasis (PsO) who are candidates for systemic therapy. For patients with chronic moderate PsO, AMGEVITA® should be used after phototherapy has been shown to be ineffective or inappropriate. **Hidradenitis suppurativa:** treatment of active moderate to severe hidradenitis suppurativa (HS) in adult and adolescent patients (12 to 17 years of age weighing ≥ 30 kg), who have not responded to conventional therapy (including systemic antibiotics).

Adult uveitis: treatment of non-infectious uveitis (intermediate, posterior, and panuveitis) in adult patients with inadequate response to corticosteroids or as corticosteroid-sparing treatment in corticosteroid-dependent patients. **Pediatric uveitis:** treatment of chronic non-infectious anterior uveitis in pediatric patients from 2 years of age who have had an inadequate response to or are intolerant to conventional therapy, or in whom conventional therapy is inappropriate.

RECOMMENDED AMGEVITA® DOSING*,[1]

Rheumatoid arthritis (RA) / Psoriatic arthritis (PsA) /Ankylosing spondylitis (AS)

- 40 mg every other week

Adult Crohn's disease (CD) / Adult ulcerative colitis (UC)

- Week 0 = 160 mg; Week 2 = 80 mg; then 40 mg every other week beginning Week 4

For patients with CD who experience a disease flare, dose escalation may be considered.

Plaque psoriasis (PsO) / Adult uveitis / Adolescent hidradenitis suppurativa (HS) (12–17 years of age weighing ≥ 30 kg)

- Week 0 = 80 mg; then 40 mg every other week beginning Week 1

In adolescent HS patients with inadequate response to AMGEVITA® 40 mg every other week, an increase in dosing frequency to 40 mg every week may be considered.

Pediatric Crohn's disease (CD)

- Week 0 = 160 mg; Week 2 = 80 mg; then 20 mg every other week beginning Week 4

For pediatric CD patients who experience a disease flare or non-response, dose escalation to 40 mg every other week may be considered.

Pediatric ulcerative colitis (UC) (5 to 17)

- Patient weight < 40 kg: Week 0=80 mg; Week 2=40 mg; then either 40 mg every other week or 20 mg every week beginning Week 4
- Patient weight ≥ 40 kg: Week 0=160 mg; Week 2=80 mg; then either 80 mg every other week or 40 mg every week beginning Week 4

Adult hidradenitis suppurativa (HS)

- Week 0 = 160 mg; Week 2 = 80 mg; then 40 mg weekly beginning Week 4

Pediatric uveitis (≥ 2 years of age; in combination with methotrexate) / Polyarticular juvenile idiopathic arthritis (JIA) (≥ 2 years of age)

- Patient weight 10 kg to < 30 kg: 20 mg every other week

JIA patients: A dose of 10 mg every other week can be considered for patients weighing 10 to < 15 kg.

- Patient weight ≥ 30 kg: 40 mg every other week

Pediatric uveitis patients: When initiated in patients ≥ 6 years of age, an optional loading dose of 40 mg for patients < 30 kg or 80 mg for patients ≥ 30 kg may be administered one week prior to the start of maintenance therapy.

Please consult the Product Monograph at https://www.amgen.ca/amgevita_pm.pdf for contraindications, warnings, precautions, adverse reactions, interactions, dosing, and conditions of clinical use.

The Product Monograph can also be obtained by calling Amgen Medical Information at 1-866-502-6436.

*Please see the Product Monograph for complete dosing and administration information.

REFERENCES:

1. AMGEVITA® Product Monograph. Amgen Canada. September 9, 2022.

2. HUMIRA® Product Monograph. AbbVie Corporation. September 16, 2022.