

Best-Value Biological Medicine (ADALIMUMAB): Amgevita®

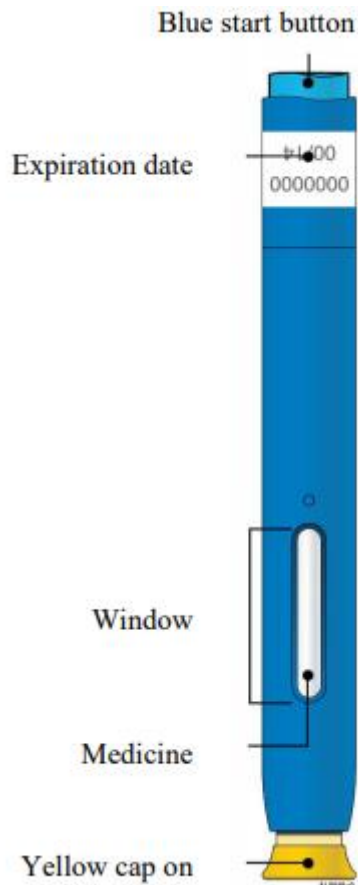
Information for Healthcare Professionals

The MMP recommends Amgevita® as a Best-Value Biological (BVB) Medicine for adalimumab. Prescribing Amgevita® will lead to significant savings for the health service, in the order of millions of euros.

The following presentations of Amgevita®, available on the High Tech Arrangement, are recommended as best-value biological (BVB) medicines:

- Amgevita® 40 mg pre-filled pen
- Amgevita® 40 mg pre-filled syringe

Amgevita® 40 mg pre-filled pen



- Each pack contains two pre-filled pens (PFP), each containing 40 mg of adalimumab.
- The needle cover of the PFP is made from dry natural rubber, which is a derivative of latex. Amgevita® 40 mg PFP is therefore **not** suitable for patients with a latex allergy.
- It is supplied as a clear and colourless to slightly yellow solution.

Storage

- Amgevita® 40 mg PFP should be stored in a refrigerator (2°C - 8°C). It should not be frozen.
- The PFP should be kept in the outer packaging in order to protect it from light.
- A single Amgevita® 40 mg PFP may be stored at a temperature up to a maximum of 25°C for a period of up to 14 days. The PFP must be protected from light, and discarded if not used within the 14-day period.

Dose Administration

- The patient information leaflet contains a very clear diagrammatic guide on how to administer a dose from the PFP.
- Delivery of the dose commences when the patient places the base of the pen on their skin, and presses the blue start button. At this time, the patient will hear the 1st loud click.
- The patient should continue to hold the pen against their skin until the yellow indicator fills the medication window and stops moving. A 2nd loud click will be heard several seconds later. This confirms delivery of the dose of adalimumab.
- Once the PFP is removed from the skin, the needle will be automatically covered.

Similarities between Amgevita® pre-filled pen and the reference biological medicine (Humira® pre-filled pen)

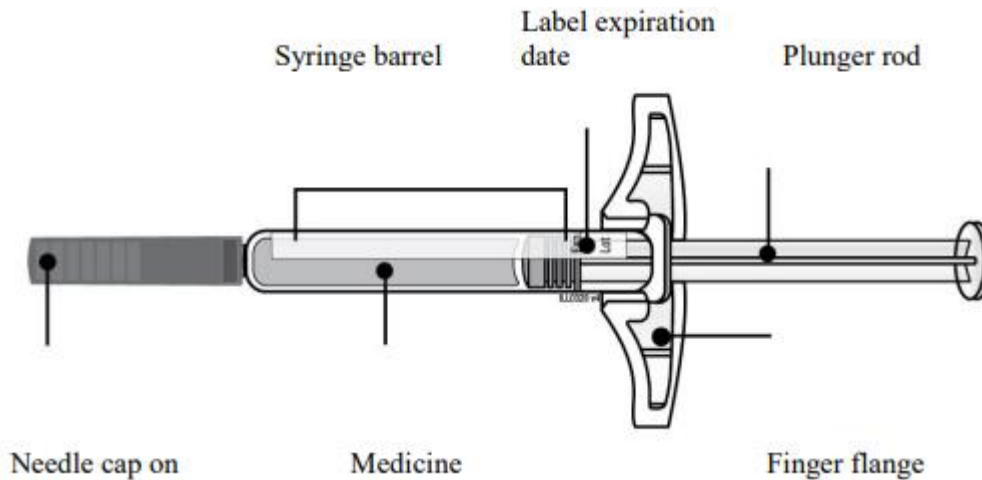
- Both Amgevita® 40 mg PFP and Humira® 40 mg PFP are citrate-free formulations.
- Both Amgevita® 40 mg PFP and Humira® 40 mg PFP have a shelf life of two years.
- Both Amgevita® 40 mg PFP and Humira® 40 mg PFP require the patient to press an activator button in order to deliver the dose of adalimumab.
- Both Amgevita® 40 mg PFP and Humira® 40 mg PFP have a safety feature; once the administration of the injection is completed, the needle retracts within the sleeve.

Differences between Amgevita® pre-filled pen and the reference biological medicine (Humira® pre-filled pen)

- Amgevita® 40 mg PFP contains 40 mg of adalimumab in 0.8 ml; Humira® 40 mg PFP contains 40 mg of adalimumab in 0.4 ml.
- For both Amgevita® 40 mg PFP and Humira® 40 mg PFP, an initial loud click signals the start of the injection, and the injection is complete when the yellow indicator fills the medication/inspection window. A 2nd loud click is only heard with Amgevita® 40 mg PFP; this confirms delivery of the dose of adalimumab.



Amgevita® 40 mg pre-filled syringe



- Each pack contains two pre-filled syringes (PFS), each containing 40 mg of adalimumab.
- No latex is used in the product or packaging; Amgevita® PFS is therefore suitable for patients with a latex allergy.
- It is supplied as a clear and colourless to slightly yellow solution.

Storage

- Amgevita® 40 mg PFS should be stored in a refrigerator (2°C - 8°C). It should not be frozen.
- The PFS should be kept in the outer packaging in order to protect it from light.
- A single Amgevita® 40 mg PFS may be stored at a temperature up to a maximum of 25°C for a period of up to 14 days. The PFS must be protected from light, and discarded if not used within the 14-day period.

Dose Administration

- The patient information leaflet contains a very clear diagrammatic guide on how to administer a dose from the PFS.
- The plunger must be pressed down fully to deliver the dose of adalimumab.
- There is no safety feature upon delivery of the dose of adalimumab; the needle does not retract within the sleeve.

Similarities between Amgevita® pre-filled syringe and the reference biological medicine (Humira® pre-filled syringe)

- Both Amgevita® 40 mg PFS and Humira® 40 mg PFS are citrate-free formulations.
- Both Amgevita® 40 mg PFS and Humira® 40 mg PFS have a shelf life of two years.

Differences between Amgevita® pre-filled syringe and the reference biological medicine (Humira® pre-filled syringe)

- Amgevita® 40 mg PFS contains 40 mg of adalimumab in 0.8 ml; Humira® 40 mg PFS contains 40 mg of adalimumab in 0.4 ml.



Amgen Ireland Patient Support Services

Amgen Ireland provides a patient support programme, Amgen Care, to patients who have been prescribed Amgevita®. This is provided by TCP Homecare at Home and Hibernian Healthcare at Home on behalf of Amgen Ireland.

The following services are available as part of the patient support programme upon referral:

- Optional nurse visit to deliver patient education on correct device handling and administration technique for Amgevita®
- Nurse educational phone call for patients who do not wish to avail of the nurse home visit
- Provision of patient information booklets and digital resources such as a patient demonstration video via a patient education website www.amgencare.ie
- Text messenger reminder service
- Sharps bin provision and waste collection service
- Dedicated patient support telephone line
- Post-home visit report emailed to referred physician
- Provision of faecal calprotectin home test kits to gastroenterology patients
- Provision of Quantiferon testing

In order to refer patients who have been prescribed Amgevita® to the patient support programme, please contact one of the following:

- TCP Homecare at 1800 211 211 or by email at homecare.pcb@tcp.ie. Alternatively, patients can be referred through the Amgen Care online referral portal: <https://www.amgencare.ie/>
- Hibernian Healthcare at Home at 01 460 4820. Alternatively, patients can be referred through the Hibernian online referral portal: <https://schedule.hahirl.com/>

In order to obtain demonstration devices and patient support materials for use in clinics, please contact TCP Homecare at 1800 211 211 or Hibernian Healthcare at Home at 01 460 4820.

▼ Amgevita® 40 mg PFP and PFS are subject to additional monitoring. Adverse reactions/events should be reported to the Health Products Regulatory Authority (HPRA) using the available methods via www.hpra.ie. Adverse reactions/events should also be reported to Amgen Limited at +44 (0) 1223 436441 or Freephone 1800 535 160.

Please report any potential quality complaint with an Amgen product by calling +44 (0) 1223 436441 or Freephone 1800 535 160. Please ensure that you keep the packaging, so Amgen are able to identify the product more easily.

References:

1. Amgevita® 40 mg solution for injection in pre-filled syringe, Amgevita® 40 mg solution for injection in pre-filled pen. SmPC and PIL. Last revised 18/01/2023. Accessed at https://www.ema.europa.eu/en/documents/product-information/amgevita-epar-product-information_en.pdf on 31/03/2023.