

Best-Value Biological Medicine (ADALIMUMAB 40 mg): Amgevita®¹

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® 40 mg, 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.
- No latex is used in the product or packaging; Amgevita® 40 mg PFP is therefore suitable for patients with a latex allergy.
- It is supplied as a clear and colourless to slightly yellow solution.

¹ This product information sheet is reflective of the revised formulation (i.e. high-concentration) of Amgevita® 40 mg pre-filled pen and syringe that was added to the High Tech Arrangement on 1 November 2024.

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)

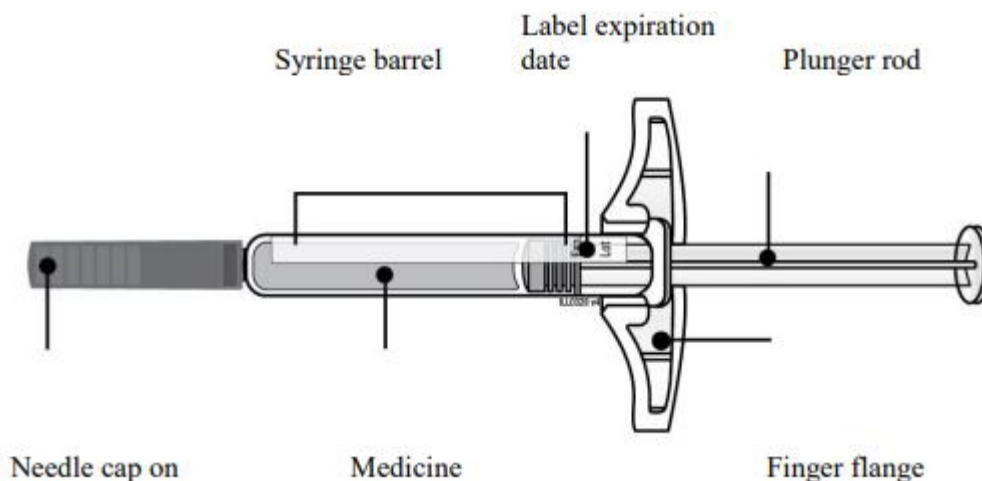
- Both Amgevita® 40 mg PFP and Humira® 40 mg PFP contain 40 mg of adalimumab in 0.4 ml.
- Both Amgevita® 40 mg PFP and Humira® 40 mg PFP are citrate-free formulations.
- Both Amgevita® 40 mg PFP and Humira® 40 mg PFP may be stored at a temperature up to a maximum of 25°C for a period of up to 14 days, after which they should not be refrigerated again. Both PFPs must be protected from light, and discarded if not used within the 14-day period.
- 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 has a shelf life of three years; Humira® 40 mg PFP has a shelf life of two years.
- 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 PFP has a 27-gauge needle; Humira® 40 mg PFP has a 29-gauge needle.



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.
- The patient should not attempt to recap the syringe with the needle cap.

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 contain 40 mg of adalimumab in 0.4 ml.
- 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 29-gauge needle.
- Both Amgevita® 40 mg PFS and Humira® 40 mg PFS may be stored at a temperature up to a maximum of 25°C for a period of up to 14 days, after which they should not be refrigerated again. Both PFS must be protected from light, and discarded if not used within the 14-day period.
- Both Amgevita® 40 mg PFS and Humira® 40 mg PFS do not have a safety feature to guard the needle upon delivery of the dose of adalimumab.

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

- Amgevita® 40 mg PFS has a shelf life of three years; Humira® 40 mg PFS has a shelf life of two years.



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 by the prescribing healthcare professional:

- Optional nurse visit to deliver patient education on correct device handling and administration technique for Amgevita®, dosing information, storage of medicine, waste disposal and adverse event reporting. Up to two home visits are funded as part of the patient support programme.
- Delivery of an Amgen Care patient support pack, including digital resources such as access to Amgevita® patient demonstration video
- Text messenger reminder service to aid adherence
- Sharps bin provision and waste collection service
- Dedicated patient support telephone line
- Post-home visit report emailed to referring healthcare professional
- 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.amgencarehcp.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.

References:

1. Amgen Europe B.V. Amgevita® 40 mg solution for injection in a pre-filled syringe, Amgevita® 40 mg solution for injection in a pre-filled pen. Summary of Product Characteristics. Last updated 08/10/2024. Accessed at www.ema.europa.eu on 31/12/2024.