

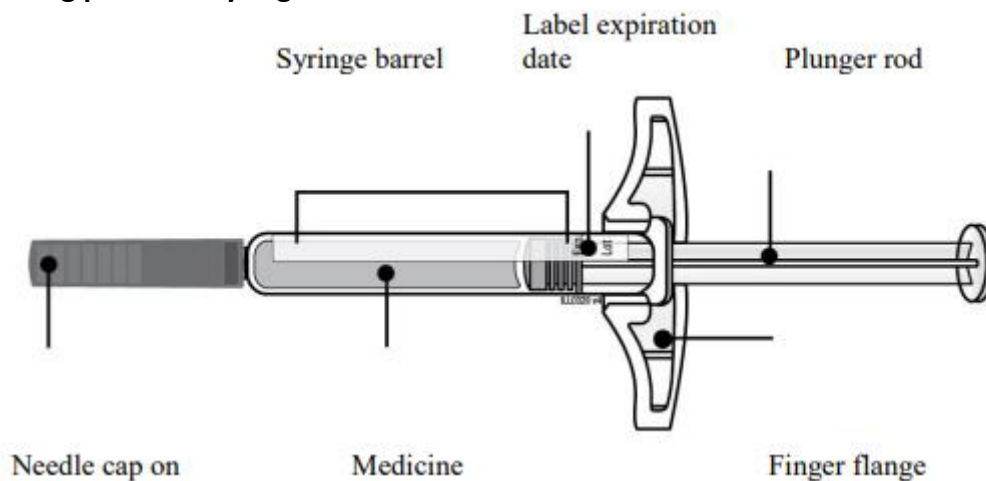
Best-Value Biological Medicine (ADALIMUMAB 20 mg): Amgevita®

Information for Healthcare Professionals

The MMP recommends Amgevita® as the Best-Value Biological (BVB) Medicine for adalimumab 20 mg solution for injection. Prescribing Amgevita® will lead to significant savings for the health service.

Amgevita® 20 mg pre-filled syringe ▼¹ is recommended as the best-value biological (BVB) medicine for adalimumab 20 mg solution for injection on the High Tech Arrangement.

Amgevita® 20 mg pre-filled syringe



- Each pack contains one pre-filled syringe (PFS), each containing 20 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® 20 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® 20 mg PFS may be stored at a temperature of 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.

¹ ▼ This medicinal product is subject to additional monitoring (see page 3 for further information)

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

- Both Amgevita® 20 mg PFS and Humira® 20 mg PFS are citrate-free formulations.
- Both Amgevita® 20 mg PFS and Humira® 20 mg PFS have a shelf life of two years.
- Both Amgevita® 20 mg PFS and Humira® 20 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® 20 mg PFS contains 20 mg of adalimumab in 0.4 ml; Humira® 20 mg PFS contains 20 mg of adalimumab in 0.2 ml.

Amgen Ireland Patient Support Services

Amgen Ireland provides a patient support programme Amgen Care, to patients who have been prescribed Amgevita® 20 mg PFS. This is provided by TCP Homecare 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:

- Nurse home 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 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.

▼ Amgevita® 20 mg PFS is 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® 20 mg solution for injection in pre-filled syringe. SmPC and PIL. Last revised 12/03/2020. Accessed at https://www.ema.europa.eu/en/documents/product-information/amgevita-epar-product-information_en.pdf on 28/04/2021.