

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

Information for Healthcare Professionals

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

Yuflyma^{®1} 20 mg pre-filled syringe (PFS) is recommended as a best-value biological (BVB) medicine for adalimumab 20 mg solution for injection on the High Tech Arrangement.

Yuflyma® is a biosimilar medicine. This means that Yuflyma® is highly similar to another biological medicine (the reference medicine) that is already authorised in the European Union. The reference medicine for Yuflyma® is Humira®.

Yuflyma® 20 mg pre-filled syringe



- Each pack contains two PFS; each PFS contains 20 mg of adalimumab.
- Each pack contains two alcohol pads.
- No latex is used in the product or packaging; Yuflyma® 20 mg PFS is therefore suitable for patients with a latex allergy.
- It is supplied as a clear to slightly opalescent, colourless to pale brown solution.
- Each PFS is equipped with a 29-gauge needle.

Storage

- Yuflyma® 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.

¹Please refer to the Summary of Product Characteristics of Yuflyma® for full prescribing information.



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A single Yuflyma® 20 mg PFS may be stored at temperatures up to a maximum of 25°C for a period of up to 31 days. The PFS must be protected from light, and discarded if not used within the 31-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 Yuflyma® 20 mg pre-filled syringe and the reference biological medicine (Humira® 20 mg pre-filled syringe)

- Both Yuflyma® 20 mg PFS and Humira® 20 mg PFS contain 20 mg of adalimumab in 0.2 mL.
- Both Yuflyma[®] 20 mg PFS and Humira[®] 20 mg PFS are citrate-free formulations.
- Both Yuflyma® 20 mg PFS and Humira® 20 mg PFS have a 29-gauge needle.
- Both Yuflyma® 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 Yuflyma® 20 mg pre-filled syringe and the reference biological medicine (Humira® 20 mg pre-filled syringe)

- Yuflyma® 20 mg PFS has a shelf life of three years; Humira® 20 mg PFS has a shelf life of two years.
- Yuflyma® 20 mg PFS may be stored at temperatures up to a maximum of 25°C for a period of up to 31 days; the PFS must be protected from light, and discarded if not used within the 31-day period. Humira® 20 mg PFS may be stored at temperatures 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.





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Celltrion Healthcare Patient Support Services

Celltrion Healthcare provides a patient support service to patients who have been prescribed Yuflyma®. This is provided by Hibernian Healthcare at Home on behalf of Celltrion Healthcare.

The following services are available as part of the patient support service:

- Home visit nurse support: this includes training on the Yuflyma® administration device and education on the biological medicine, e.g. storage, travelling tips.
- Nurse educational phone call for patients who do not wish to avail of the nurse home visit.
- Provision of a patient starter pack to include a disease guide, instruction leaflet, travel card, safety
 information and access to an online training video.
- Access to a dedicated patient support line.
- Text message reminder service to aid adherence.
- Sharps management service this includes the provision of sharps bins and waste collection.
- Provision of faecal calprotectin home test kits to gastroenterology patients.
- Provision of QuantiFeron testing.
- Yuflyma® training device: This is a training syringe and is available to healthcare professionals.

In order to refer a patient who has been prescribed Yuflyma® to the patient support programme, please use the Hibernian Healthcare at Home online portal https://schedule.hahirl.com/.

If you have not registered on the Hibernian portal previously, please contact Hibernian Healthcare at Home at 01 460 4820 or by email at info@hibernianhealth.com and access and support will be provided.

Healthcare professionals wishing to obtain a training syringe, product information or support materials for use in clinics should contact their local Celltrion Product Specialist or Celltrion Healthcare Ireland, Unit 26, Arrow Building, Old Belgard Road, Tallaght Dublin 24 ND70.

Email: <u>Enquiry_IE@celltrionhc.com</u>

Phone: 01 223 4026

References:

- 1. Celltrion Healthcare Hungary Kft. Yuflyma® 20 mg solution for injection in pre-filled syringe. Summary of Product Characteristics. Last updated 27/03/2025. Accessed at www.ema.europa.eu on 29/05/2025.
- 2. AbbVie Deutschland GmbH Co. KG. Humira® 20 mg solution for injection in pre-filled syringe. Summary of Product Characteristics. Last updated 20/03/2025. Accessed at www.ema.europa.eu on 29/05/2025.