

Best-Value Biological Medicine (ADALIMUMAB): Yuflyma[®]

Information for Healthcare Professionals

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

The following presentation of Yuflyma[®]▼^{1,2}, available on the High Tech Arrangement, is recommended as a best-value biological medicine:

- Yuflyma[®] 40 mg pre-filled pen

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- Each pack contains two pre-filled pens (PFP), each containing 40 mg of adalimumab.
- Each pack also contains two alcohol pads.
- No latex is used in the product or packaging; Yuflyma[®] 40 mg PFP is therefore suitable for patients with a latex allergy.
- It is supplied as a clear to slightly opalescent, colourless to pale brown solution.
- Each PFP is equipped with a 29-gauge needle.

Storage

- Yuflyma[®] 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 Yuflyma[®] 40 mg PFP may be stored at a temperature up to a maximum of 25°C for a period of up to 30 days. The PFP must be protected from light, and discarded if not used within the 30-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 green base of the pen firmly on their skin, and pushes down. At this time, the patient will hear the 1st loud click.

¹ ▼ This medicinal product is subject to additional monitoring.

² Please refer to the Summary of Product Characteristics of Yuflyma[®] for full prescribing information.

HSE-Medicines Management Programme

- The patient should continue to hold the pen firmly against their skin and listen for the 2nd loud click. For best practice, the patient should continue to hold the pen firmly against the skin and count slowly to five to ensure the full dose is injected.
- The medication window should be filled by a blue plunger rod with a grey top. This confirms delivery of the dose of adalimumab. The pen can then be removed from the skin.
- Once the injection is complete, the needle retracts within the sleeve as the device is removed from the skin.

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

- Both Yuflyma® 40 mg PFP and Humira® 40 mg PFP contain 40 mg of adalimumab in 0.4 ml.
- Both Yuflyma® 40 mg PFP and Humira® 40 mg PFP are citrate-free.
- Both Yuflyma® 40 mg PFP and Humira® 40 mg PFP have a shelf-life of two years.
- Both Yuflyma® 40 mg PFP and Humira® 40 mg PFP have a safety feature; once administration of the injection is completed, the needle retracts within the sleeve.

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

- Delivery of the dose from the Yuflyma® 40 mg PFP commences when the patient places the green base of the pen firmly on their skin and pushes down. For the Humira® 40 mg PFP, the patient is required to press an activator button in order to deliver the dose of adalimumab.
- For both Yuflyma® 40 mg PFP and Humira® 40 mg PFP, an initial loud click signals the start of the injection. For Humira® 40 mg PFP, the injection is complete when the yellow indicator fills the medication/inspection window.
- As well as having a visual indication that the injection is completed, a 2nd loud click is heard to confirm that the dose of adalimumab has been delivered from a Yuflyma® PFP.



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 pen and is available to healthcare professionals.

In order 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 4604820 or by email at info@hibernianhealth.com and access and support will be provided.

In order to obtain training pens and patient support materials for use in clinics please contact:

Celltrion Healthcare Ireland, Unit 26, Arrow Building, Old Belgard Road, Tallaght Dublin 24 ND70.

- Email: Enquiry_IE@celltrionhc.com
- Phone: (087) 3386213

References:

1. Yuflyma® 40 mg solution for injection in pre-filled syringe, Yuflyma® 40 mg solution for injection in pre-filled pen. SmPC and PIL. Last revised 17/06/2021. Accessed at https://www.ema.europa.eu/en/documents/product-information/yuflyma-epar-product-information_en.pdf on 10/10/2021.