## **HSE-Medicines Management Programme**



## 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<sup>®1</sup>, available on the High Tech Arrangement, is recommended as a best-value biological medicine:

Yuflyma® 40 mg pre-filled pen

## Yuflyma® 40 mg pre-filled pen



- 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 31 days. The PFP 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 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 1<sup>st</sup> loud click.
- The patient should continue to hold the pen firmly against their skin and listen for the 2<sup>nd</sup> 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.

<sup>&</sup>lt;sup>1</sup> Please refer to the Summary of Product Characteristics of Yuflyma® for full prescribing information.

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- 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 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)

- Yuflyma® 40 mg PFP has a shelf life of three years; Humira® 40 mg PFP has a shelf life of two years.
- 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 2<sup>nd</sup> loud click is heard to confirm that the dose of adalimumab has been delivered from a Yuflyma<sup>®</sup> PFP.



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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 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 <a href="https://schedule.hahirl.com/">https://schedule.hahirl.com/</a>.

If you have not registered on the Hibernian portal previously, please contact Hibernian Healthcare at Home at 01 4604820 or by email at <a href="mailto:info@hibernianhealth.com">info@hibernianhealth.com</a> 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 30/01/2023. Accessed at <a href="https://www.ema.europa.eu/en/documents/product-information/yuflyma-epar-product-information">https://www.ema.europa.eu/en/documents/product-information/yuflyma-epar-product-information</a> en.pdf on 31/03/2023.