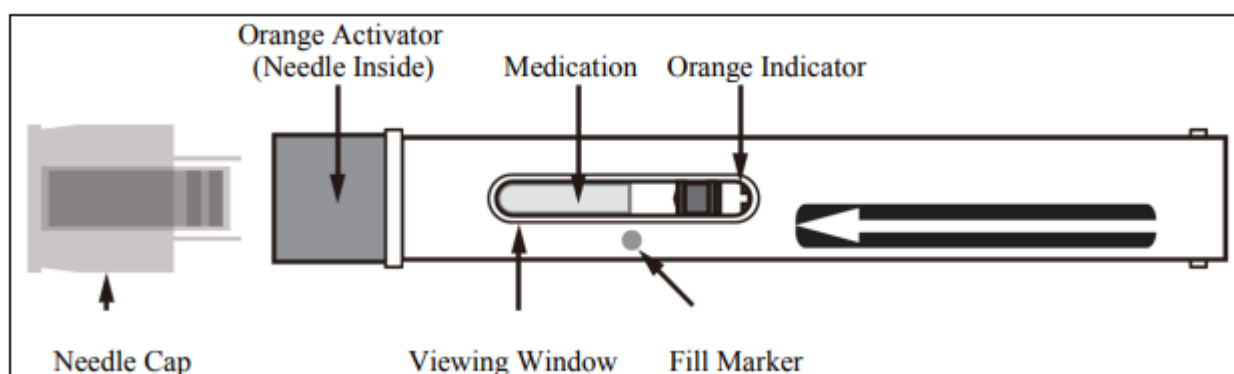


**Best-Value Biological Medicine (ADALIMUMAB): Hulio®****Information for Healthcare Professionals**

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

The following presentations of Hulio®▼<sup>1</sup>, available on the High Tech Arrangement, are recommended as best-value biological (BVB) medicines:

- Hulio® 40 mg solution for injection in pre-filled pen
- Hulio® 40 mg solution for injection in pre-filled syringe

**Hulio® 40 mg solution for injection in 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; Hulio® 40 mg PFP is therefore suitable for patients with a latex allergy.
- It is supplied as a clear or slightly opalescent, colourless to pale brownish-yellow solution.

**Storage**

- Hulio® 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 Hulio® 40 mg PFP may be stored at temperatures up to a maximum of 25°C for a period of up to eight weeks. The PFP must be protected from light, and discarded if not used within the eight-week period.

<sup>1</sup> ▼ This medicinal product is subject to additional monitoring

## 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 orange base of the pen 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 against their skin until one, or all, of the following occur, which confirm delivery of the dose of adalimumab:
  - the orange indicator fills the viewing window and stops moving
  - a 2<sup>nd</sup> loud click is heard
  - ten seconds have passed.
- Once the PFP is removed from the skin, the needle will be automatically covered.

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

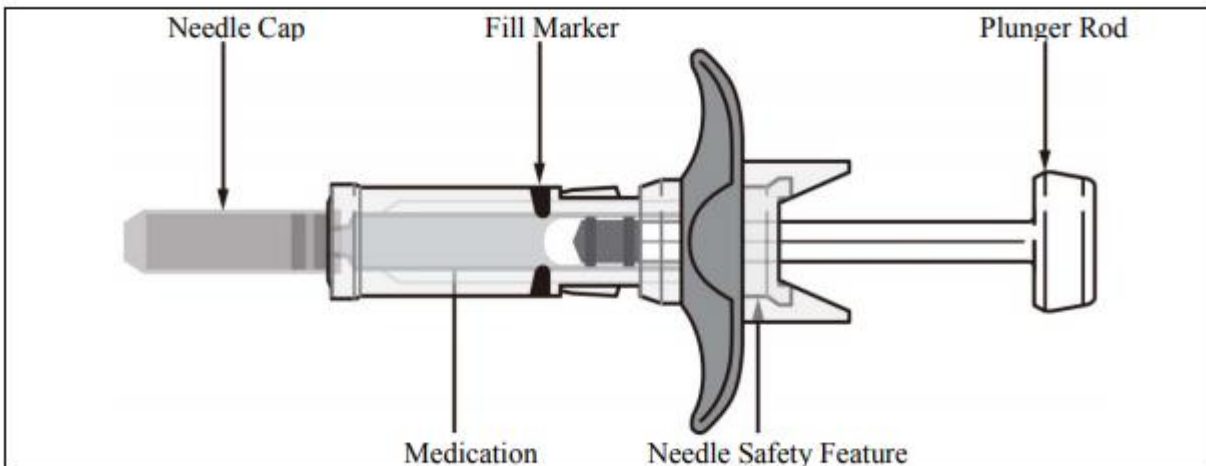
- Both Hulio® 40 mg PFP and Humira® 40 mg PFP are citrate-free formulations.
- Both Hulio® 40 mg PFP and Humira® 40 mg PFP have a safety feature; once the administration of the injection is completed, the needle retracts within the sleeve.

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

- Hulio® 40 mg PFP contains 40 mg of adalimumab in 0.8 ml; Humira® 40 mg PFP contains 40 mg of adalimumab in 0.4 ml.
- Hulio® 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 Hulio® 40 mg PFP commences when the patient places the orange base of the pen on their skin and pushes down (note: Hulio is pressure activated i.e. it does not have an activator button). 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 Hulio® 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 orange (Hulio®) or yellow (Humira®) indicator fills the viewing/inspection window. A 2<sup>nd</sup> loud click is only heard with Hulio® 40 mg PFP; this confirms delivery of the dose of adalimumab.



## Hulio® 40 mg solution for injection in pre-filled syringe



- Each pack contains two pre-filled syringes (PFS), each containing 40 mg of adalimumab.
- Each pack also contains two alcohol pads.
- No latex is used in the product or packaging; Hulio® 40 mg PFS is therefore suitable for patients with a latex allergy.
- It is supplied as a clear or slightly opalescent, colourless to pale brownish-yellow solution.

### **Storage**

- Hulio® 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 Hulio® 40 mg PFS may be stored at temperatures up to a maximum of 25°C for a period of up to eight weeks. The PFS must be protected from light, and discarded if not used within the eight-week period.

### **Dose Administration**

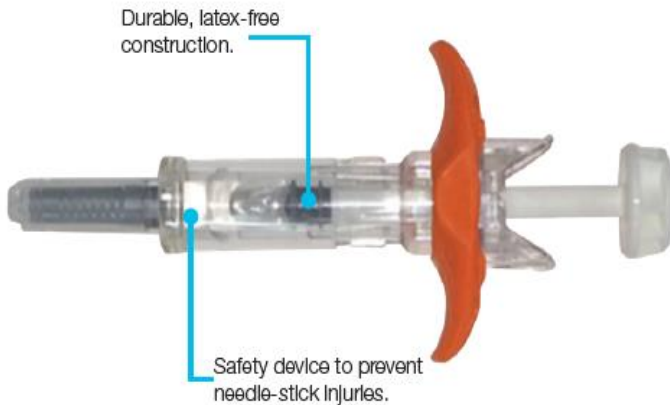
- The patient information leaflet contains a very clear diagrammatic guide on how to administer a dose from the PFS.
- The plunger must be pressed down fully to deliver the dose of adalimumab.
- The needle will retract into the body of the syringe when the patient lifts their thumb from the plunger.

### **Similarities between Hulio® pre-filled syringe and the reference biological medicine (Humira® pre-filled syringe)**

- Both Hulio® 40 mg PFS and Humira® 40 mg PFS are citrate-free formulations.

### **Differences between Hulio® pre-filled syringe and the reference biological medicine (Humira® pre-filled syringe)**

- Hulio® 40 mg PFS contains 40 mg of adalimumab in 0.8 ml; Humira® 40 mg PFS contains 40 mg of adalimumab in 0.4 ml.
- Hulio® 40 mg PFS has a shelf life of three years; Humira® 40 mg PFS has a shelf life of two years.
- Hulio® 40 mg PFS has a safety feature upon delivery of the dose of adalimumab; the needle will retract into the body of the syringe when the plunger is released. Humira® 40 mg PFS does not have a safety feature.



## Mylan Ireland Patient Support Services

Mylan Ireland provide a patient support service to patients who have been prescribed Hulo<sup>®</sup>. This is provided by Hibernian Healthcare at Home on behalf of Mylan Ireland.

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

- Optional nurse visit to deliver patient education on correct device handling and administration technique for Hulo<sup>®</sup>
- Provision of QuantiFERON testing
- Sharps bin provision and waste collection service
- Provision of faecal calprotectin home test kits to gastroenterology patients

**In order to avail of the patient support services for patients who have been prescribed Hulo<sup>®</sup>, please use the Hibernian Healthcare at Home online portal [www.schedule.hahirl.com](http://www.schedule.hahirl.com).**

**If you have not registered on the Hibernian portal previously, please contact Hibernian Healthcare at Home on 01-4604820 or by email at [info@hibernianhealth.com](mailto: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 Mylan Ireland Limited, Newenham Court, Northern Cross, Malahide Road, Dublin 17 D17 XC99 at +353-1-8322250. For medical information queries, please contact [info@mylan.co.uk](mailto:info@mylan.co.uk)

### References:

1. Hulo<sup>®</sup> EPAR – Product Information. Last revised 05/12/2022. Accessed at [https://www.ema.europa.eu/en/documents/product-information/hulo-epar-product-information\\_en.pdf](https://www.ema.europa.eu/en/documents/product-information/hulo-epar-product-information_en.pdf) on 31/03/2023.