

Best-Value Biological Medicine (ADALIMUMAB): Hulio®

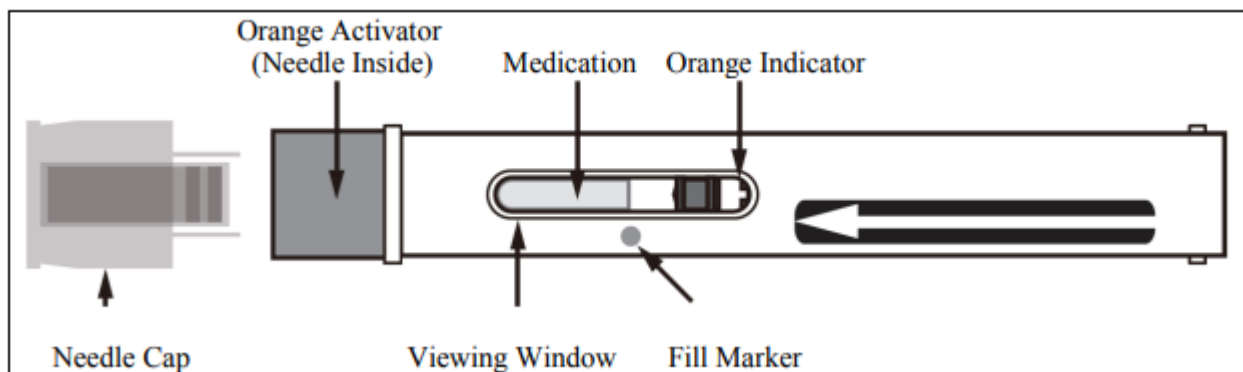
Information for Healthcare Professionals

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®▼¹, 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 14 days. The PFP must be protected from light, and discarded if not used within the 14-day period.

¹ ▼ 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 1st 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 2nd 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)

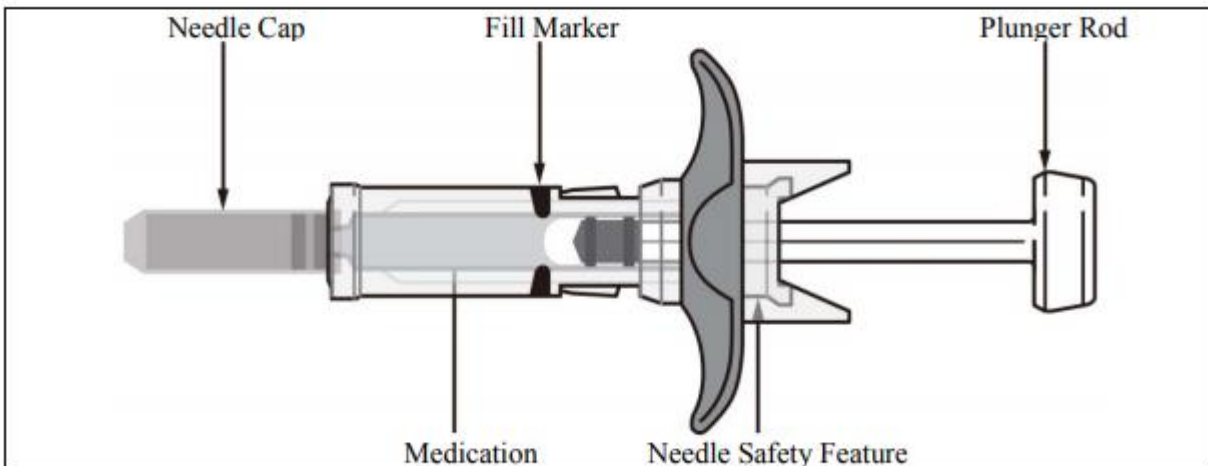
- Both Hulio® 40 mg PFP and Humira® 40 mg PFP are citrate-free formulations.
- Both Hulio® 40 mg PFP and Humira® 40 mg PFP have a shelf life of two years.
- Both Hulio® 40 mg PFP and Humira® 40 mg PFP have a safety feature; once the administration of the injection is completed, the needle retracts within 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.
- 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 2nd 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 14 days. The PFS must be protected from light, and discarded if not used within the 14-day period.

Dose Administration

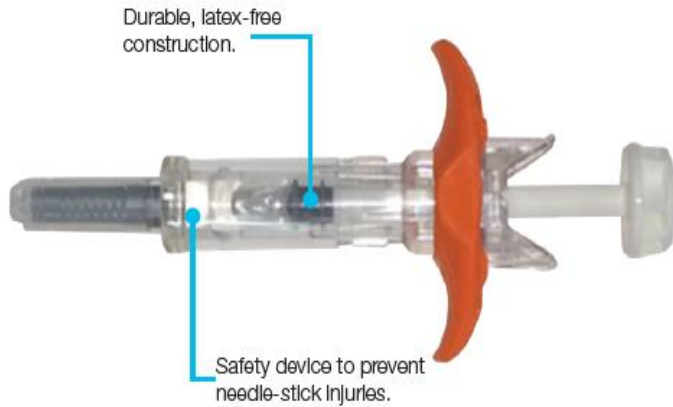
- The patient information leaflet contains a very clear diagrammatic guide on how to administer a dose from the PFS.
- The plunger must be pressed down fully to deliver the dose of adalimumab.
- The needle will retract into the body of the syringe when the patient lifts their thumb from the plunger.

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.
- Both Hulio® 40 mg PFS and Humira® 40 mg PFS have a shelf life of two years.
- Both Hulio® 40 mg PFS and Humira® 40 mg PFS have a safety feature which guards the needle upon delivery of the dose of adalimumab.

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.



Mylan Ireland Patient Support Services

Mylan Ireland provide a patient support service to patients who have been prescribed Hulo®. 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®
- 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®, please use the Hibernian Healthcare at Home online portal 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, 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

References:

1. Hulo® EPAR – Product Information. Last revised 11/11/2019. Accessed at https://www.ema.europa.eu/en/documents/product-information/hulo-epar-product-information_en.pdf on 28/02/2020.