

**Best-Value Biological Medicine (ADALIMUMAB): Imraldi®<sup>1</sup>****Information for Healthcare Professionals**

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

The following presentations of Imraldi®, available on the High Tech Arrangement, are recommended as best-value biological medicines:

- Imraldi® 40 mg pre-filled pen
- Imraldi® 40 mg pre-filled syringe

**Imraldi® 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; Imraldi® 40 mg PFP is therefore suitable for patients with a latex allergy.
- It is supplied as a clear and colourless solution.

**Storage**

- Imraldi® 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 Imraldi® 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. Once the PFP reaches room temperature, it should not be returned to the refrigerator, but used within the 31-day period.

<sup>1</sup> This product information sheet is reflective of the revised formulation (i.e. low-volume, citrate-free) of Imraldi® 40 mg pre-filled pen and syringe that was added to the High Tech Arrangement on 1 April 2023.

## **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 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 the yellow indicator fills the medication window and stops moving. A 2<sup>nd</sup> loud click will be heard once the indicator has filled the medication window and stopped moving. This confirms delivery of the dose of adalimumab.
- Once the injection is complete, the needle retracts within the sleeve as the device is removed from the skin.

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

- Both Imraldi® 40 mg PFP and Humira® 40 mg PFP contain 40 mg of adalimumab in 0.4 ml.
- Both Imraldi® 40 mg PFP and Humira® 40 mg PFP are citrate-free.
- Both Imraldi® 40 mg PFP and Humira® 40 mg PFP have a shelf life of two years.
- Both Imraldi® 40 mg PFP and Humira® 40 mg PFP have a safety feature upon administration of the dose of adalimumab; once administration of the injection is complete, the needle retracts within the sleeve.
- Both Imraldi® 40 mg PFP and Humira® 40 mg PFP have a 29-gauge needle.

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

- Delivery of the dose from the Imraldi® 40 mg PFP commences when the patient places the green base of the pen 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 Imraldi® 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 yellow indicator fills the medication/inspection window. A 2<sup>nd</sup> loud click is only heard with Imraldi® 40 mg PFP; this confirms delivery of the dose of adalimumab.
- A single Imraldi® 40 mg PFP may be stored at a temperature up to a maximum of 25°C for a period of up to 31 days, after which it should not be refrigerated again. The PFP must be protected from light, and discarded if not used within the 31-day period. A single Humira® 40 mg PFP may be stored at a temperature up to a maximum of 25°C for a period of up to 14 days, after which it should not be refrigerated again. The PFP must be protected from light, and discarded if not used within the 14-day period.



## Imraldi® 40 mg 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; Imraldi® 40 mg PFS is therefore suitable for patients with a latex allergy.
- It is supplied as a clear and colourless solution.

### **Storage**

- Imraldi® 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 Imraldi® 40 mg PFS may be stored at a temperature 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. Once the PFS reaches room temperature, it should not be returned to the refrigerator, but 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.
- The needle will retract into the body of the syringe when the patient lifts their thumb from the plunger.

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

- Both Imraldi® 40 mg PFS and Humira® 40 mg PFS contain 40 mg of adalimumab in 0.4 ml.
- Both Imraldi® 40 mg PFS and Humira® 40 mg PFS are citrate-free.
- Both Imraldi® 40 mg PFS and Humira® 40 mg PFS have a shelf life of two years.
- Both Imraldi® 40 mg PFS and Humira® 40 mg PFS have a 29-gauge needle.

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

- Imraldi® 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 patient lifts their thumb from the plunger. Humira® 40 mg PFS does not have a safety feature.
- A single Imraldi® 40 mg PFS may be stored at a temperature up to a maximum of 25°C for a period of up to 31 days, after which it should not be refrigerated again. The PFS must be protected from light, and discarded if not used within the 31-day period. A single Humira® 40 mg PFS may be stored at a temperature up to a maximum of 25°C for a period of up to 14 days, after which it should not be refrigerated again. The PFS must be protected from light, and discarded if not used within the 14-day period.



## Biogen (Ireland) Limited Patient Support Services

Biogen (Ireland) Limited provide a patient support service to patients who have been prescribed Imraldi®. This is provided by Hibernian Healthcare at Home on behalf of Biogen (Ireland) Limited.

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

- Home visit nurse support: This includes training on the Imraldi® administration device and education on the biological medicine, e.g. storage, travelling tips, use of the injection diary, access to a device instruction video.
- Follow-up telephone support
- Sharps management service: This includes the provision of sharps bins and waste collection.
- Provision of travel cool bags on request
- Imraldi® patient information booklet: This includes access to an online training video and written guides on injection device administration, disease area, product information booklets, an injection diary and a travel certificate
- Imraldi® training device: This is a training pen and is available to healthcare professionals.
- “Biosimilars Made Clear” booklet: This is available in English and 10 other languages.
- Provision of QuantiFERON testing
- Provision of EUT Profile (Hep B, Hep C, HIV, Syphilis) testing
- 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 Imraldi®, 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 at 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, patient support materials for use in clinics, or information relating to faecal calprotectin testing, please contact:

- Email: [medinfo.europe@biogen.com](mailto:medinfo.europe@biogen.com)
- Phone: 01-5133333

### References:

1. Imraldi® 40 mg solution for injection in pre-filled syringe, Imraldi® 40 mg solution for injection in pre-filled pen. SmPC and PIL. Last revised 31/10/2022. Accessed [https://www.ema.europa.eu/en/documents/product-information/imraldi-epar-product-information\\_en.pdf](https://www.ema.europa.eu/en/documents/product-information/imraldi-epar-product-information_en.pdf) on 22/03/2023.