

Best-Value Biological Medicine (ADALIMUMAB): Imraldi®¹**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.

¹ 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 1st 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 2nd 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 2nd 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. 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, patient support materials for use in clinics, or information relating to faecal calprotectin testing, please contact:

- Email: 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 on 22/03/2023.