

Best-Value Biological Medicine (ADALIMUMAB): Hyrimoz®

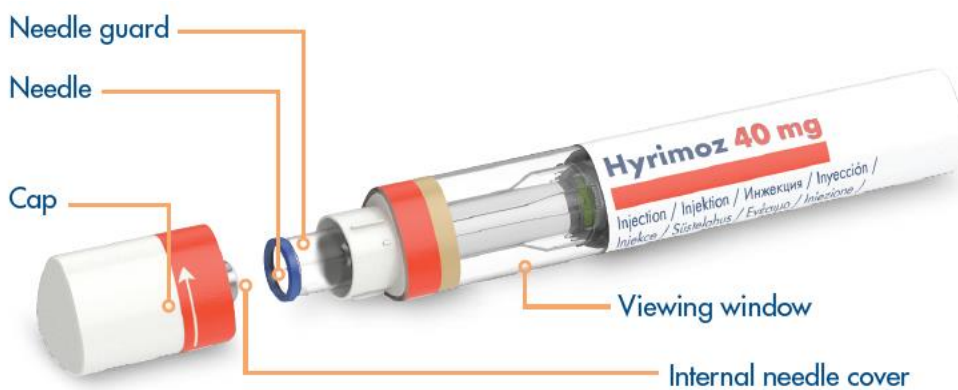
Information for Healthcare Professionals

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

The following presentation of Hyrimoz®▼¹, available on the High Tech Arrangement, is recommended as a best-value biological (BVB) medicine:

- Hyrimoz® 40 mg solution for injection in pre-filled pen

Hyrimoz® 40 mg solution for injection in pre-filled pen



- Each pack contains two pre-filled pens (PFP), each containing 40 mg of adalimumab.
- The needle cover of the PFP is made from dry natural rubber, which is a derivative of latex. Hyrimoz® 40 mg PFP is therefore **not** suitable for patients with a latex allergy.
- It is supplied as a clear or slightly opalescent, colourless to slightly yellowish solution.

Storage

- Hyrimoz® PFP 40 mg 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 Hyrimoz® 40 mg PFP may be stored at a temperature up to a maximum of 25°C for a period of up to 21 days, after which it should not be refrigerated again. The PFP must be protected from light, and discarded if not used within the 21-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 base of the pen on their skin and pushes down. At this time, the patient will hear the 1st click.
- The patient should continue to hold the pen against their skin. A 2nd click will then be heard. This indicates the injection is almost complete. After the 2nd click, the patient should check that the green indicator fills the viewing window and has stopped moving.
- The empty pen can then be removed from the skin. The viewing window should now be green in colour; this confirms that the full dose of adalimumab has been delivered.
- Once the injection is complete, the needle will automatically withdraw into the pen. The needle will not be exposed again at any point even if you press the pen down again post injection.

Similarities between Hyrimoz[®] pre-filled pen and the reference biological medicine (Humira[®] pre-filled pen)

- Both Hyrimoz[®] 40 mg PFP and Humira[®] 40 mg PFP have a safety feature upon administration of the dose of adalimumab.

Differences between Hyrimoz[®] pre-filled pen and the reference biological medicine (Humira[®] pre-filled pen)

- Hyrimoz[®] 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.
- Hyrimoz[®] 40 mg PFP contains citric acid monohydrate; Humira[®] 40 mg PFP does not contain citrate.
- Hyrimoz[®] 40 mg PFP has a 27-gauge needle; Humira[®] 40 mg PFP has a 29-gauge needle.
- A single Hyrimoz[®] 40 mg PFP may be stored at a temperature up to a maximum of 25°C for a period of up to 21 days, after which it should not be refrigerated again. The PFP must be protected from light, and discarded if not used within the 21-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.
- Hyrimoz[®] 40 mg PFP has a shelf life of 30 months; Humira[®] 40 mg PFP has a shelf life of two years.
- Delivery of the dose from the Hyrimoz[®] 40 mg PFP commences when the patient places the 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 Hyrimoz[®] 40 mg PFP, an initial loud click signals the start of the injection, and the injection is complete when the green indicator fills the viewing window. A 2nd loud click is only heard with Hyrimoz[®] 40 mg PFP; this confirms delivery of the dose of adalimumab. For 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.
- No alcohol swabs are provided with Hyrimoz[®] 40 mg PFP; two alcohol swabs are provided in a pack of Humira[®] 40 mg PFP.

Novartis Ireland Limited Patient Support Programme

Novartis Ireland Limited provide a patient support programme to patients who have been prescribed Hyrimoz® 40 mg PFP. This is provided by Hibernian Healthcare at Home on behalf of Novartis Ireland Limited.

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

- provision of a patient information pack that includes written guides on injection device administration, disease area, product information booklets, travel pass and travel letter
- nurse home visit to deliver patient education and training on Hyrimoz® administration device and education on Hyrimoz®, including storage requirements, traveling tips and access to a device instruction video
- educational phone call provided by a nurse for patients who do not wish to avail of the nurse home visit
- access to a dedicated patient support line
- text message reminder service to aid adherence
- provision of a sharps management service
- provision of QuantiFERON 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 Hyrimoz® 40 mg PFP, 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 01 460 4820 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:

- Email: medinfo.dublin@novartis.com
- Phone: 01 260 1255

▼ This medicinal product is subject to additional monitoring. Reporting suspected adverse reactions of the medicinal product is important. It allows continued monitoring of the benefit/risk of the medicinal product. All suspected adverse reactions should be reported via HPRA Pharmacovigilance Website: www.hpra.ie. Adverse events should also be reported to Novartis preferably via www.report.novartis.com or by email drugsafety.dublin@novartis.com or by calling 01 208 0612.

References:

1. Hyrimoz® EPAR – Product Information. Last revised 03/03/2022. Accessed at https://www.ema.europa.eu/en/documents/product-information/hyrimoz-epar-product-information_en.pdf on 22/06/2022.