

Best-Value Biological Medicine (ADALIMUMAB): Hukyndra®

Information for Healthcare Professionals

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

The following presentations of Hukyndra®¹, available on the High Tech Arrangement, are recommended as best-value biological medicines:

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

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

Storage

- Hukyndra® 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 Hukyndra® 40 mg PFP may be stored at a temperature 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 Please refer to the Summary of Product Characteristics of Hukyndra® for full prescribing information.

Dose Administration

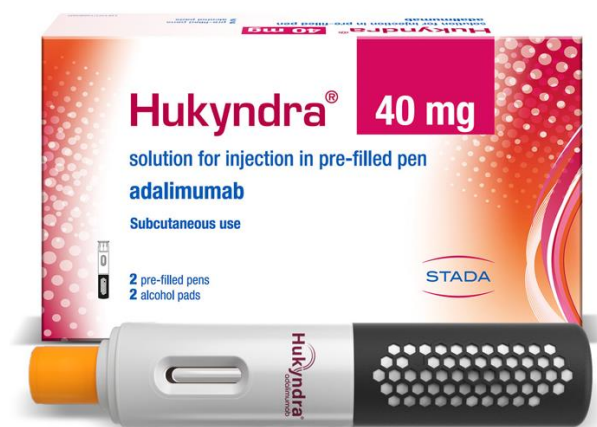
- The patient information leaflet contains a very clear diagrammatic guide on how to administer a dose from the PFP.
- Delivery of the dose commences when the patient places the orange base of the pen on their skin, and pushes down. At this time, the patient will hear the 1st loud click.
- The patient should continue to hold the pen against their skin until the orange indicator fills the medication window and stops moving. This confirms delivery of the dose of adalimumab . A 2nd loud click may be heard at this point.
- Once the injection is complete, the orange needle sleeve will cover the needle tip as the device is slowly pulled away from the skin.

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

- Both Hukyndra® 40 mg PFP and Humira® 40 mg PFP contain 40 mg of adalimumab in 0.4 ml.
- Both Hukyndra® 40 mg PFP and Humira® 40 mg PFP are citrate-free.
- Both Hukyndra® 40 mg PFP and Humira® 40 mg PFP have a shelf life of two years.
- Hukyndra® 40 mg PFP and Humira® PFP may be stored at a temperature up to a maximum of 25°C for a period of up to 14 days, after which they should not be refrigerated again. Both PFP’s must be protected from light, and discarded if not used within the 14-day period.
- Both Hukyndra® 40 mg PFP and Humira® 40 mg PFP have a safety feature upon administration of the dose of adalimumab; once administration is complete, the needle retracts within the sleeve of the PFPs.
- Both Hukyndra® 40 mg PFP and Humira® 40 mg PFP have a 29-gauge needle.

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

- Delivery of the dose from the Hukyndra® 40 mg PFP commences when the patient places the orange 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 the Hukyndra® 40 mg PFP an initial loud click signals the start of the injection, and administration of the injection is complete when the orange indicator fills the inspection window. A 2nd loud click may also be heard with Hukyndra® 40 mg PFP when administration is complete. For the 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.



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

Storage

- Hukyndra® 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 Hukyndra® 40 mg PFS may be stored at a temperature 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 the Hukyndra® pre-filled syringe and the reference biological medicine (Humira® pre-filled pen)

- Both Hukyndra® 40 mg PFS and Humira® 40 mg PFS contains 40 mg of adalimumab in 0.4 ml.
- Both Hukyndra® 40 mg PFS and Humira® 40 mg PFS are citrate-free.
- Both Hukyndra® 40 mg PFS and Humira® 40 mg PFS have a shelf life of two years.
- Hukyndra® 40 mg PFS and Humira® PFS may be stored at a temperature up to a maximum of 25°C for a period of up to 14 days, after which they should not be refrigerated again. Both PFS's must be protected from light, and discarded if not used within the 14-day period.
- Both Hukyndra® 40 mg PFS and Humira® 40 mg PFS have a 29-gauge needle.

Differences between the Hukyndra® pre-filled syringe and the reference biological medicine (Humira® pre-filled syringe)

- Hukyndra® 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.



Clonmel Healthcare Patient Support Services

Clonmel Healthcare provide a patient support service to patients who have been prescribed Hukyndra®. This service is provided by TCP Homecare at Home on behalf of Clonmel Healthcare.

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

- Provision of a patient support programme that includes patient information booklets on injection device administration, disposal and side-effects, and access to an injection device administration video
- Virtual consultations delivered by nurses to provide education and training to patients on Hukyndra®, including injection administration, storage requirements and travelling tips, with the option for an in-person consultation if required
- Access to a freephone patient support line
- Sharps management service: This includes the provision of sharps bins and waste collection.
- 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 Hukyndra®, please contact TCP Homecare at Home at 01 429 1280 or by email at homecarePCB@tcp.ie.

In order to obtain training pens and patient support materials for use in clinics, please contact:

- Email: medicalinformation@clonmel-health.ie
- Phone: 052 61 77777

References:

1. Hukyndra® 40 mg solution for injection in pre-filled syringe, Hukyndra® 40 mg solution for injection in pre-filled pen. SmPC and PIL. Last revised 09/03/2023. Accessed https://www.ema.europa.eu/en/documents/product-information/hukyndra-epar-product-information_en.pdf on 20/06/2023.