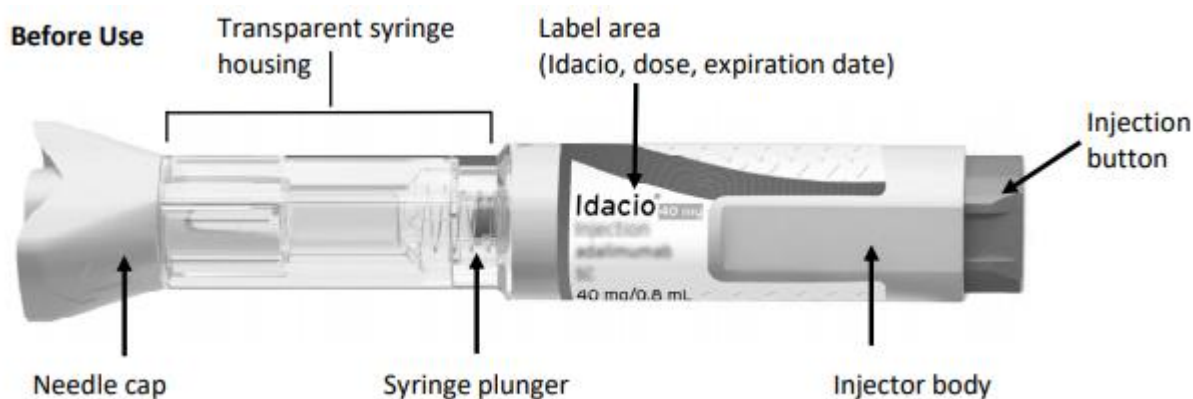


Best-Value Biological Medicine (ADALIMUMAB): Idacio®**Information for Healthcare Professionals**

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

The following presentations of Idacio®▼¹, available on the High Tech Arrangement, are recommended as best-value biological (BVB) medicines:

- Idacio 40 mg solution for injection in pre-filled pen
- Idacio 40 mg solution for injection in pre-filled syringe

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

Storage

- Idacio® 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 Idacio® 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 ▼ 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.
- To deliver the dose of adalimumab, the patient should push and hold the PFP firmly against the skin until the safety guard is fully depressed; this will unlock the injection button. The patient should then push the injection button. At this time, the patient will hear a loud click.
- The patient should continue to hold the pen against their skin until the syringe plunger moves all the way down to the bottom. When the syringe plunger has moved to the bottom and stops moving, continue holding the pen against the skin for five seconds, and then lift the pen from the skin.
- Once the injection is complete, the safety guard will slide down and lock into place to protect the needle.

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

- Both Idacio® 40 mg PFP and Humira® 40 mg PFP have a shelf life of two years.
- Both Idacio® 40 mg PFP and Humira® 40 mg PFP have a safety feature upon administration of the dose of adalimumab.
- Both Idacio® 40 mg PFP and Humira® 40 mg PFP require the patient to press an activator button in order to deliver the dose of adalimumab.

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

- Idacio® 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.
- Idacio® 40 mg PFP contains sodium citrate; Humira® 40 mg PFP does not contain citrate.

Images of Idacio® 40 mg PFP and packaging

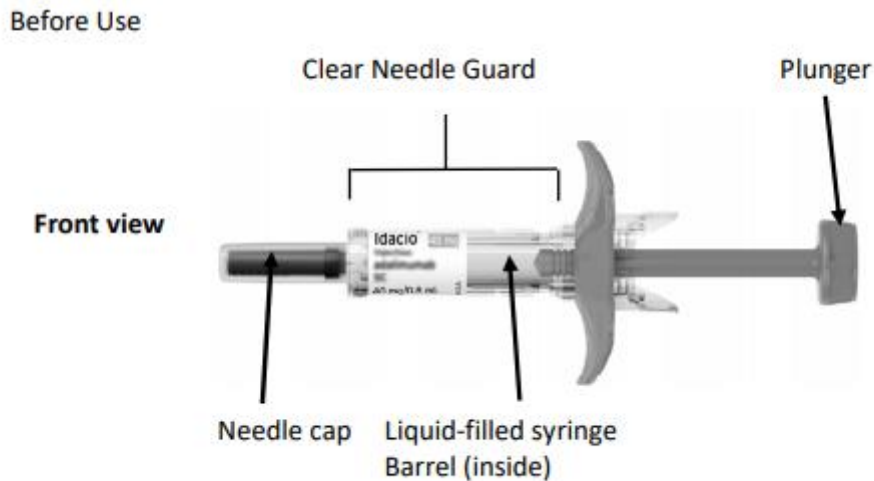
Before Use



After Use



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

Storage

- Idacio® 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 Idacio® 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.
- When the plunger reaches the end, the patient should not remove the needle from their skin; they should release their thumb up. This will allow the needle to move up into the clear needle guard, and cover the entire needle.

Similarities between Idacio® pre-filled syringe and the reference biological medicine (Humira® pre-filled syringe)

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

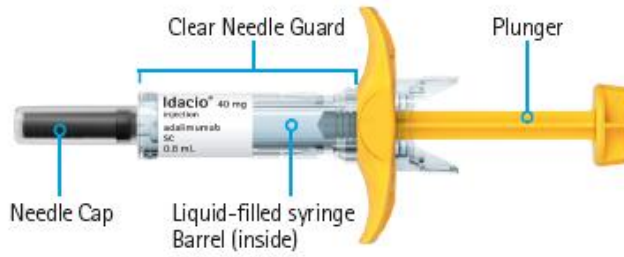
Differences between Idacio® pre-filled syringe and the reference biological medicine (Humira® pre-filled syringe)

- Idacio® 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.
- Idacio® 40 mg PFS contains sodium citrate; Humira® 40 mg PFS does not contain citrate.

Images of Idacio® PFS and packaging

Before Use

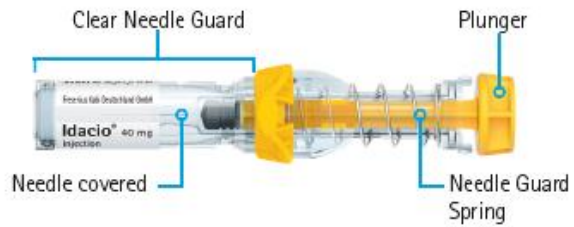
Front view

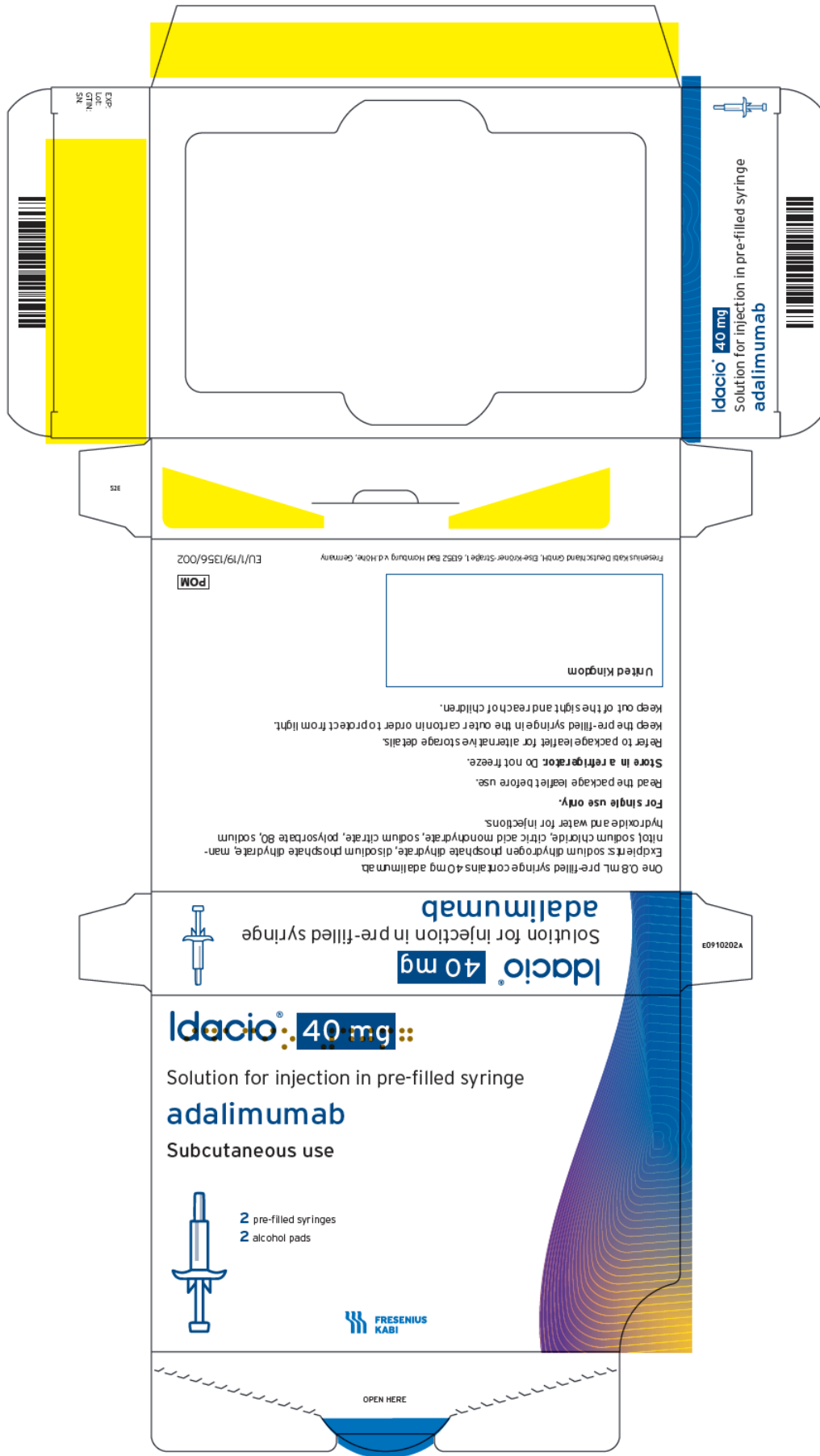


Back view



After Use





Fresenius Kabi Ireland Patient Support Services

Fresenius Kabi Ireland provide a patient support service to patients who have been prescribed Idacio[®]. This is provided by TCP Homecare at Home on behalf of Fresenius Kabi Ireland.

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

- Home visit nurse support: This includes training on the Idacio[®] administration device and education on the biological medicine e.g. storage, travelling tips.
- Follow-up telephone support
- Sharps management service: This includes the provision of sharps bins and waste collection.
- Idacio[®] patient starter kit: This includes access to an online training video.
- 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 Idacio[®], contact TCP Homecare at Home:

Freephone: 1800 810 020 or Tel: (01) 4291828

Email: homecarepcb@tcp.ie

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

Fresenius Kabi Ltd, Unit 3B Fingal Bay, Balbriggan, Co Dublin.

Phone: (01) 841 3030

Email: FK-enquiries.Ireland@fresenius-kabi.com

References:

1. Idacio[®] EPAR – Product Information. Last revised 28/01/2020. Accessed at https://www.ema.europa.eu/en/documents/product-information/idacio-epar-product-information_en.pdf on 28/02/2020.