Best-Value Biological Medicine (ADALIMUMAB): Humira® 40 mg

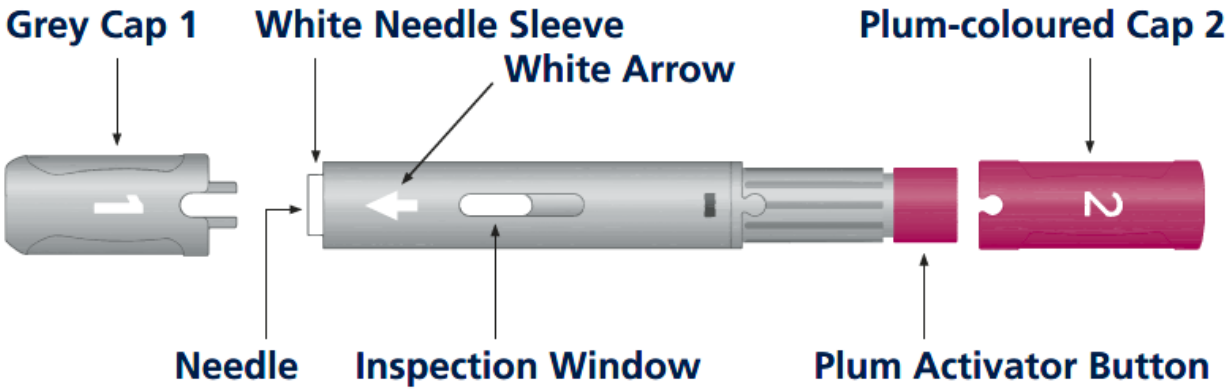
Information for Healthcare Professionals

The MMP recommends Humira® 40 mg as a Best-Value Biological (BVB) Medicine for adalimumab. Prescribing Humira® 40 mg will lead to significant savings for the health service, in the order of millions of euros.

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

- Humira® 40 mg solution for injection in pre-filled pen
- Humira® 40 mg solution for injection in pre-filled syringe

Humira® 40 mg pre-filled pen



- Each pack contains two pre-filled pens (PFP), containing 40 mg of adalimumab in 0.4 ml of solution for injection.
- Each pack also contains two alcohol pads.
- No latex is used in the product or packaging; Humira® 40 mg PFP is therefore suitable for patients with a latex allergy.
- It is supplied as a clear, colourless solution.
- Each PFP is equipped with a 29-gauge needle.
- Humira® 40 mg PFP does not contain citrate.
- Humira® 40 mg PFP has a shelf life of two years.

Storage

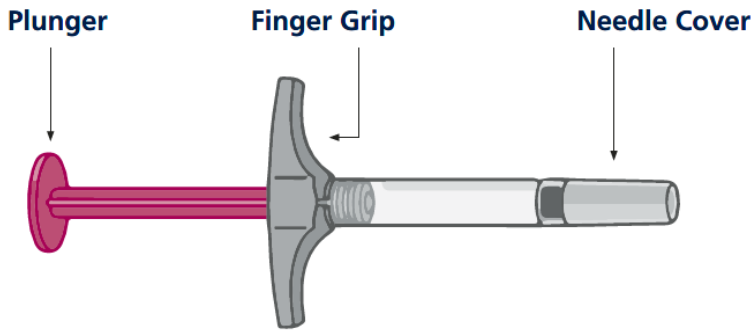
- Humira® 40 mg PFP should be stored in a refrigerator (2°C - 8°C). It should not be frozen.
- The PFP should be kept in the outer carton in order to protect it from light.
- A single Humira® 40 mg PFP may be stored at a temperature up to a maximum of 25°C for a period of up to 14 days.
- The PFP must be protected from light, and discarded if not used within the 14-day period.

[1] Please refer to the Summary of Product Characteristics of Humira® available at www.medicines.ie 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.
- The patient should place the white needle sleeve of the pen straight (90° angle) against the injection site, and firmly push down. Delivery of the dose commences when the patient presses the plum activator button. At this time, the patient will hear a loud click to signal the start of the injection.
- The patient should continue to hold the pen firmly against their skin. The injection is complete when the yellow indicator in the inspection window has stopped moving.
- Once the injection is complete, the PFP should be pulled slowly from the skin. The white needle sleeve will then cover the needle tip.
- Please refer to the Patient Information Leaflet (PIL) for further information.

Humira® 40 mg pre-filled syringe



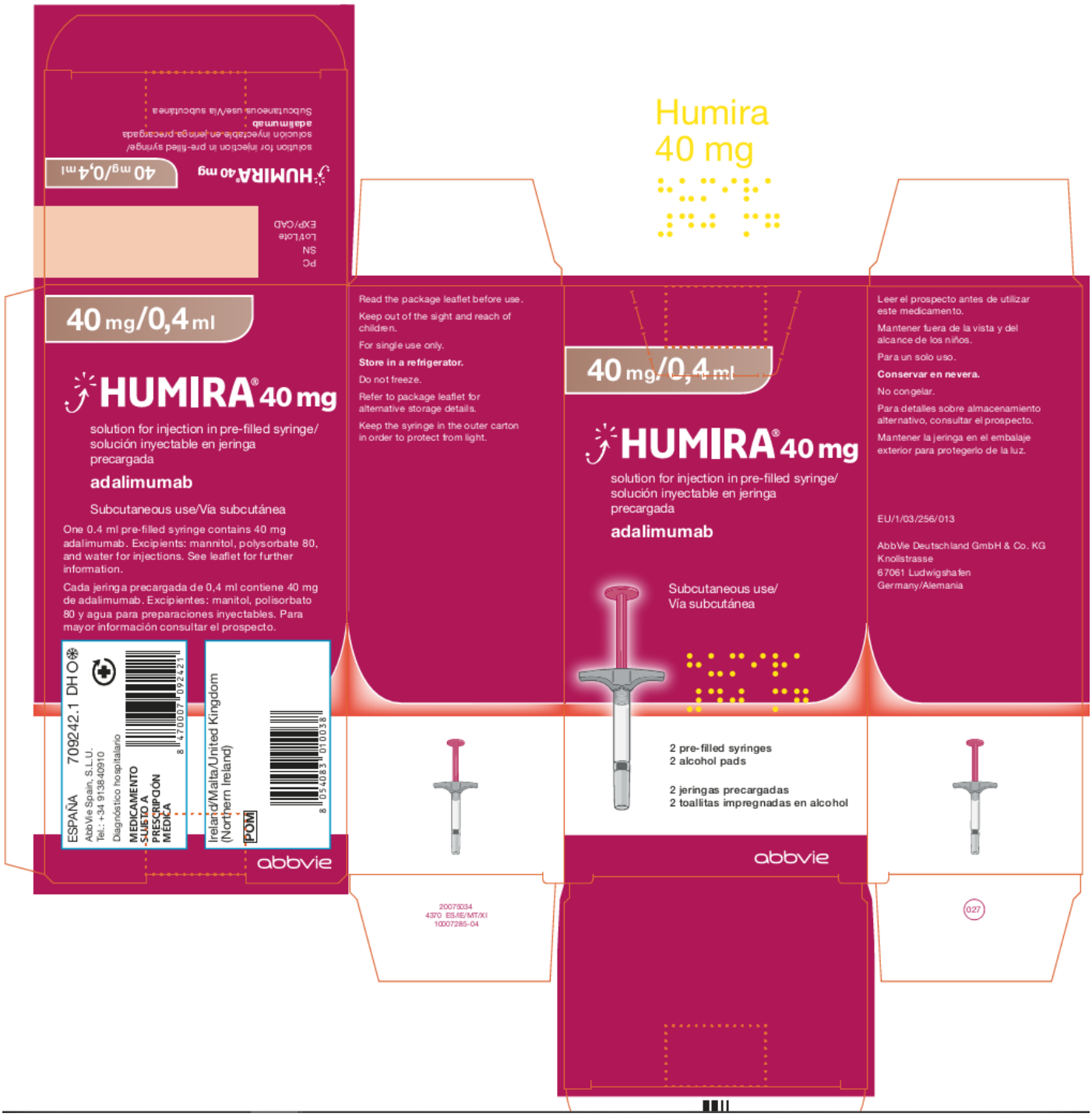
- Each pack contains two pre-filled syringes (PFS), containing 40 mg of adalimumab in 0.4 ml of solution for injection.
- Each pack also contains two alcohol pads.
- No latex is used in the product or packaging; Humira® 40 mg PFS is therefore suitable for patients with a latex allergy.
- It is supplied as a clear, colourless solution.
- Each PFS is equipped with a 29-gauge needle.
- Humira® 40 mg PFS does not contain citrate.
- Humira® 40 mg PFS has a shelf life of two years.

Storage

- Humira® 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 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. The PFP 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, until all of the liquid is injected and the PFS is empty. This is to ensure that the full dose of adalimumab is delivered.
- Humira® 40 mg PFS does not have a safety feature to guard the needle upon administration of the dose of adalimumab. The needle does not retract within the sleeve.
- Please refer to the Patient Information Leaflet (PIL) for further information.


Humira
40 mg
40 mg/0,4 ml
HUMIRA® 40 mg
solution for injection in pre-filled syringe/
solución inyectable en jeringa precargada
adalimumab
Subcutaneous use/Vía subcutánea
One 0.4 ml pre-filled syringe contains 40 mg adalimumab. Excipients: mannitol, polysorbate 80, and water for injections. See leaflet for further information.
Cada jeringa precargada de 0,4 ml contiene 40 mg de adalimumab. Excipientes: manitol, polisorbato 80 y agua para preparaciones inyectables. Para mayor información consultar el prospecto.
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Diagnóstico hospitalario
MEDICAMENTO SUJETO A PRESCRIPCIÓN MÉDICA
Ireland/Malta/United Kingdom (Northern Ireland)
POM
abbvie
Read the package leaflet before use.
Keep out of the sight and reach of children.
For single use only.
Store in a refrigerator.
Do not freeze.
Refer to package leaflet for alternative storage details.
Keep the syringe in the outer carton in order to protect from light.
Subcutaneous use/
Vía subcutánea
2 pre-filled syringes
2 alcohol pads
2 jeringas precargadas
2 toallitas impregnadas en alcohol
abbvie
20079334
4370 ES/IE/MT/XI
10007285-04
Leer el prospecto antes de utilizar este medicamento.
Mantener fuera de la vista y del alcance de los niños.
Para un solo uso.
Conservar en nevera.
No congelar.
Para detalles sobre almacenamiento alternativo, consultar el prospecto.
Mantener la jeringa en el embalaje exterior para protegerlo de la luz.
EU/1/03/256/013
AbbVie Deutschland GmbH & Co. KG
Knollstrasse
67061 Ludwigshafen
Germany/Alemania
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AbbVie Ireland Limited

AbbVie Ireland Limited provides a patient support service to patients who have been prescribed Humira®. This is provided by Point of Care Limited on behalf of AbbVie Ireland Limited.

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

- Home visit nurse support: this includes training on the Humira® administration device and education on the biological medicine e.g. storage, travelling tips. This can also be delivered remotely, if required.
- Provision of a patient information pack to include self-injection administration guide and information on travelling with your medication.
- Access to a dedicated patient website.
- Access to a dedicated patient support phoneline.
- SMS reminder service to aid adherence.
- Sharps management service - this includes the provision of sharps bins and waste collection.
- Provision of a cool bag to support patient travel.
- Provision of faecal calprotectin home test kits to gastroenterology patients.
- Provision of QuantiFeron screening.
- Humira® training device: This is a training pen and is available to healthcare professionals.

To refer a patient who has been prescribed Humira® to the patient support programme or obtain training pens, please contact 1800 200 573 or www.abbviecare.ie

References:

1. Humira® 40 mg solution for injection in pre-filled pen, Humira® 40 mg solution for injection in pre-filled syringe. SmPC and PIL. Last revised 11/10/2022. Accessed at https://www.ema.europa.eu/en/documents/product-information/humira-epar-product-information_en.pdf on 29/06/2023.