

Best-Value Biological Medicine (ETANERCEPT): Benepali®**Information for Healthcare Professionals**

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

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

- Benepali® 25 mg pre-filled syringe
- Benepali® 50 mg pre-filled pen
- Benepali® 50 mg pre-filled syringe

Benepali® 50 mg pre-filled pen

- Each pack contains four pre-filled pens (PFP), each containing 50 mg of etanercept.
- No latex is used in the product or packaging; Benepali® 50 mg PFP is therefore suitable for patients with a latex allergy.
- The solution should be clear to slightly opalescent, colourless or pale yellow, and may contain small white or almost transparent particles of protein.
- The injection should not be used if the solution is discoloured, cloudy, or if particles other than those described above are present.

Storage

- Benepali® 50 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 Benepali® 50 mg PFP may be stored at a temperature up to a maximum of 30°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.

Dose Administration

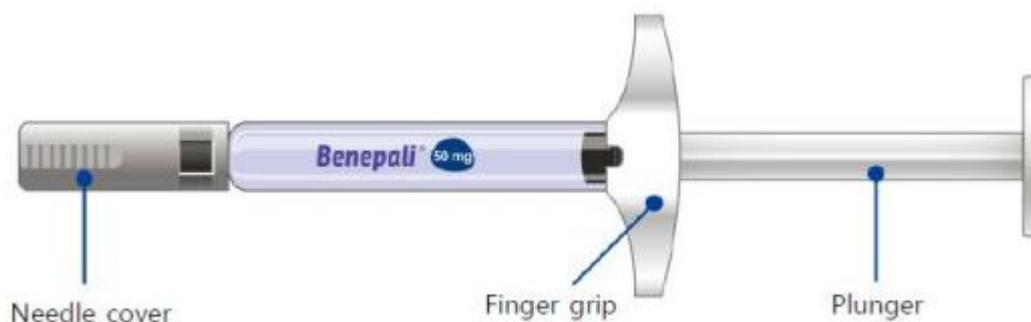
- The patient information leaflet contains a very clear diagrammatic guide on how to administer a dose from the PFP.
- Delivery of the dose commences when the patient places the base of the pen on their skin and pushes down. At this time, the patient will hear the 1st click.
- The patient should continue to hold the pen against their skin. A 2nd click will then be heard. After the 2nd click the patient should count slowly to 15 to ensure the injection is complete.
- The empty pen can then be removed from the skin. The viewing window should now be yellow in colour; this confirms that the full dose of etanercept has been delivered.
- Once the injection is complete, a needle guard will completely cover the needle.

Differences between Benepali[®] pre-filled pen and the reference biological medicine (Enbrel[®] Myclic pre-filled pen)

- Benepali[®] 50 mg PFP is latex-free; the needle cap of Enbrel[®] 50 mg Myclic PFP is made from dry natural rubber, which is a derivative of latex. It, therefore, cannot be used in patients with a latex allergy.
- Benepali[®] 50 mg PFP has a shelf life of three years; Enbrel[®] 50 mg Myclic PFP has a shelf life of 30 months.
- Delivery of the dose from the Benepali[®] 50 mg PFP commences when the patient places the base of the pen on their skin, and pushes down. For the Enbrel[®] 50 mg Myclic PFP, the patient is required to press an activator button at the top of the pen in order to deliver the dose of etanercept.
- For both Benepali[®] 50 mg PFP and Enbrel[®] 50 mg Myclic PFP, an initial click signals the start of the injection, and the injection is complete when the yellow (Benepali[®] 50 mg PFP) or purple (Enbrel[®] 50 mg Myclic PFP) indicator fills the viewing/inspection window.
- For Benepali[®] 50 mg PFP, the patient should leave the pen pushed against the skin for 15 seconds after the 2nd click to ensure the injection is complete; the Enbrel[®] 50 mg Myclic PFP can be lifted from the skin once the 2nd click is heard.
- The solution in Benepali[®] 50 mg PFP should be clear to slightly opalescent, colourless or pale yellow, and may contain small white or almost transparent particles of protein. The solution in Enbrel[®] 50 mg Myclic PFP should be clear to slightly opalescent, colourless to pale yellow or pale brown, and may contain small translucent or white particles of protein.
- No alcohol swabs are provided with Benepali[®] 50 mg PFP; four alcohol swabs are provided in a pack of Enbrel[®] 50 mg Myclic PFP.

HSE-Medicines Management Programme

Benepali® 25 mg and 50 mg pre-filled syringe



- Each pack contains four pre-filled syringes (PFS), each containing 25 or 50 mg of etanercept.
- No latex is used in the product or packaging; Benepali® PFS is therefore suitable for patients with a latex allergy.
- The solution should be clear to slightly opalescent, colourless or pale yellow, and may contain small white or almost transparent particles of protein.
- The injection should not be used if the solution is discoloured, cloudy, or if particles other than those described above are present.

Storage

- Benepali® 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 Benepali® PFS may be stored at a temperature up to a maximum of 30°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 etanercept.
- There is no safety feature on the Benepali® PFS. The PFS should be disposed of in an approved sharps container immediately after administration.

Differences between Benepali® pre-filled syringe and the reference biological medicine (Enbrel® pre-filled syringe)

- Benepali® PFS is latex-free; the needle cap of Enbrel® PFS is made from dry natural rubber, which is a derivative of latex. It, therefore, cannot be used in patients with a latex allergy.
- Benepali® PFS has a shelf life of three years; Enbrel® PFS has a shelf life of 30 months.
- The solution in Benepali® PFS should be clear to slightly opalescent, colourless or pale yellow, and may contain small white or almost transparent particles of protein. The solution in Enbrel® PFS should be clear to slightly opalescent, colourless to pale yellow or pale brown, and may contain small translucent or white particles of protein.
- No alcohol swabs are provided with Benepali® PFS; four alcohol swabs are provided in a pack of Enbrel® PFS.



Biogen (Ireland) Limited Patient Support Services

Biogen (Ireland) Limited provide a patient support service to patients who have been prescribed Benepali®. 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 Benepali® administration device and education on the biological medicine e.g. storage, travelling tips, access to a device instruction video.
- Follow-up telephone support
- Sharps management service: This includes the provision of sharps bins and waste collection.
- Benepali® patient starter kit: This includes access to an online training video and written guides on injection device administration.
- Benepali® training device: This is a training pen, and is available to healthcare professionals.
- “Biosimilars Made Clear” booklet: This is available in English and 11 other languages.
- Provision of QuantiFERON testing
- Provision of EUT Profile (Hep B, Hep C, HIV, Syphilis) testing

In order to avail of the patient support services for patients who have been prescribed Benepali®, 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 and patient support materials for use in clinics, please contact:

- Email: medinfo.europe@biogen.com
- Phone: 01-5133333

References:

1. Benepali® 25 mg solution for injection in pre-filled syringe, Benepali® 50 mg solution for injection in pre-filled syringe, Benepali® 50 mg solution for injection in pre-filled pen. SmPC and PIL. Last revised 13/02/2023. Accessed at https://www.ema.europa.eu/documents/product-information/benepali-epar-product-information_en.pdf on 31/03/2023.