

## 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 25°C for a period of up to 28 days. The PFP must be protected from light, and discarded if not used within the 28-day period. Once the PFP reaches room temperature, it should not be returned to the refrigerator, but used within the 28-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 1<sup>st</sup> click.
- The patient should continue to hold the pen against their skin. A 2<sup>nd</sup> click will then be heard. After the 2<sup>nd</sup> 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<sup>®</sup> pre-filled pen and the reference biological medicine (Enbrel<sup>®</sup> Myclic pre-filled pen)***

- Benepali<sup>®</sup> 50 mg PFP is latex-free; the needle cap of Enbrel<sup>®</sup> 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<sup>®</sup> 50 mg PFP has a shelf life of three years; Enbrel<sup>®</sup> 50 mg Myclic PFP has a shelf life of 30 months.
- Delivery of the dose from the Benepali<sup>®</sup> 50 mg PFP commences when the patient places the base of the pen on their skin, and pushes down. For the Enbrel<sup>®</sup> 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<sup>®</sup> 50 mg PFP and Enbrel<sup>®</sup> 50 mg Myclic PFP, an initial click signals the start of the injection, and the injection is complete when the yellow (Benepali<sup>®</sup> 50 mg PFP) or purple (Enbrel<sup>®</sup> 50 mg Myclic PFP) indicator fills the viewing/inspection window.
- For Benepali<sup>®</sup> 50 mg PFP, the patient should leave the pen pushed against the skin for 15 seconds after the 2<sup>nd</sup> click to ensure the injection is complete; the Enbrel<sup>®</sup> 50 mg Myclic PFP can be lifted from the skin once the 2<sup>nd</sup> click is heard.
- The solution in Benepali<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> 50 mg PFP; four alcohol swabs are provided in a pack of Enbrel<sup>®</sup> 50 mg Myclic PFP.

## 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 25°C for a period of up to 28 days. The PFS must be protected from light, and discarded if not used within the 28-day period. Once the PFS reaches room temperature, it should not be returned to the refrigerator, but used within the 28-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.

**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](http://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](mailto: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](mailto: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 23/02/2021. Accessed at [https://www.ema.europa.eu/documents/product-information/benepali-epar-product-information\\_en.pdf](https://www.ema.europa.eu/documents/product-information/benepali-epar-product-information_en.pdf) on 28/02/2021.