

Best-Value Biological Medicine (ETANERCEPT): Erelzi®

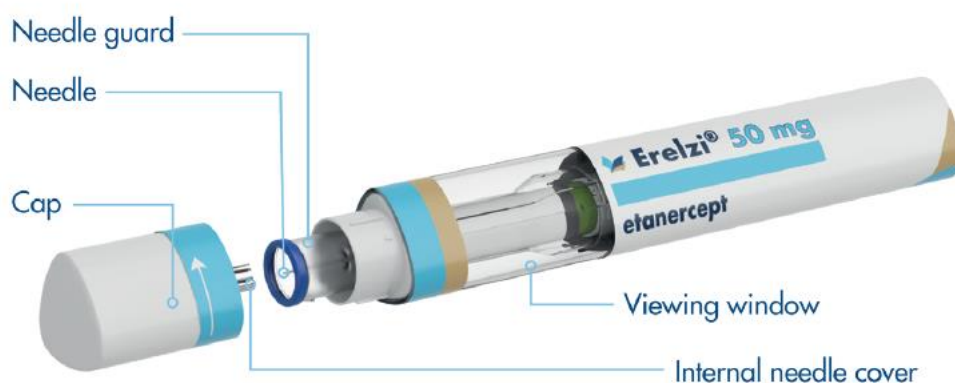
Information for Healthcare Professionals

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

The following presentation of Erelzi®^{▼1,2}, available on the High Tech Arrangement, is recommended as a best-value biological (BVB) medicine:

- Erelzi® 50 mg pre-filled pen

Erelzi® 50 mg pre-filled pen



- Each pack contains four pre-filled pens (PFP), each containing 50 mg of etanercept.
- The solution should be clear or slightly opalescent, colourless to slightly yellowish and may contain small translucent or white particles of protein.
- The internal cover, within the PFP, is made from dry natural rubber, which is a derivative of latex. Erelzi® 50 mg PFP is therefore **not** suitable for patients with a latex allergy.

Storage

- Erelzi® 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 Erelzi® 50 mg PFP may be stored at temperatures up to a maximum of 25°C for a period of up to four weeks; after which it should not be refrigerated again. The PFP must be protected from light, and discarded if not used within four weeks of removal from refrigeration.

¹ ▼ This medicinal product is subject to additional monitoring.

² Please refer to the Summary of Product Characteristics of Erelzi® for full prescribing information.

Dose Administration

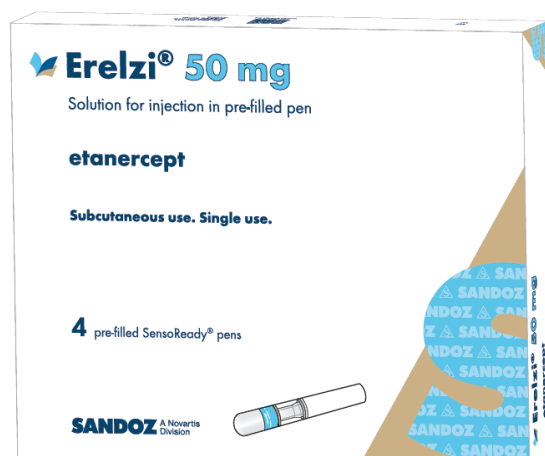
- The patient information leaflet contains a very clear diagrammatic guide on how to administer a dose from the PFP.
- Delivery of the dose commences when the patient places the base of the pen on their skin and pushes down. At this time, the patient will hear the 1st click.
- The patient should continue to hold the pen against their skin. A 2nd click will then be heard. This indicates the injection is almost complete. After the 2nd click, the patient should check that the green indicator fills the viewing window and has stopped moving.
- The empty pen can then be removed from the skin. The viewing window should now be green in colour; this confirms that the full dose of etanercept has been delivered.
- Once the injection is complete, the needle retracts within the sleeve.

Similarities between Erelzi® 50 mg pre-filled pen and the reference biological medicine (Enbrel® 50 mg Myclic pre-filled pen)

- For both Erelzi® 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 green (Erelzi® 50 mg PFP) or purple (Enbrel® 50 mg Myclic PFP) indicator fills the viewing/inspection window.
- Both Erelzi® 50 mg PFP and Enbrel® 50 mg PFP have a safety feature to guard the needle upon administration of the dose of etanercept.
- Both the internal needle cover within the Erelzi® 50 mg PFP, and the needle cap of Enbrel® 50 mg Myclic PFP, are made from dry natural rubber, which is a derivative of latex. They, therefore, **cannot** be used in patients with a latex allergy.

Differences between Erelzi® 50 mg pre-filled pen and the reference biological medicine (Enbrel® 50 mg Myclic pre-filled pen)

- Erelzi® 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 Erelzi® 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.
- The solution in Erelzi® 50 mg PFP should be clear or slightly opalescent, colourless to slightly yellowish and may contain small translucent or white 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 Erelzi® 50 mg PFP; four alcohol swabs are provided in a pack of Enbrel® 50 mg Myclic PFP.



Novartis Ireland Limited Patient Support Programme

Novartis Ireland Limited provide a patient support programme to patients who have been prescribed Erelzi® 50 mg PFP. This is provided by Hibernian Healthcare at Home on behalf of Novartis Ireland Limited.

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

- Provision of a patient information pack that includes written guides on injection device administration, disease area and product information booklets
- Nurse home visit to deliver patient education and training on Erelzi® administration device and education on Erelzi®, including storage requirements, traveling tips and access to a device instruction video
- Educational phone call provided by a nurse for patients who do not wish to avail of the nurse home visit
- Access to a dedicated patient support line
- Provision of a sharps management service. This includes the provision of sharps bins and waste collection.
- Provision of QuantiFERON testing
- Erelzi® training device: This is a training pen, and is available to healthcare professionals

In order to avail of the patient support services for patients who have been prescribed Erelzi® 50 mg PFP, 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 01 460 4820 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 Novartis Ireland Ltd:

- Email: medinfo.dublin@novartis.com
- Phone: 01 260 1255

▼ This medicinal product is subject to additional monitoring. Reporting suspected adverse reactions of the medicinal product is important. It allows continued monitoring of the benefit/risk profile of the medicinal product. All suspected adverse reactions should be reported via HPRA Pharmacovigilance Website: www.hpra.ie. Adverse events could also be reported to Novartis preferably via www.report.novartis.com or by email: drugsafety.dublin@novartis.com or by calling 01 208 0612.

References:

1. Erelzi® 50 mg solution for injection in pre-filled pen. SmPC and PIL. Last revised 10/06/2021. Accessed at https://www.ema.europa.eu/en/documents/product-information/erelzi-epar-product-information_en.pdf on 20/01/2022.