

**Best-Value Biological Medicine (Long-acting granulocyte-colony stimulating factors):  
Ziextenzo® (Pegfilgrastim)**

**Information for Healthcare Professionals**

The MMP recommends Ziextenzo® as a Best-Value Biological (BVB) Medicine for the long-acting granulocyte-colony stimulating factors. Prescribing Ziextenzo® will lead to significant savings for the health service.

The following presentation of Ziextenzo®, available on the High Tech Arrangement, is recommended as a best-value biological (BVB) medicine:

- Ziextenzo® solution for injection pre-filled syringe (PFS) 6 mg/0.6 ml.

Ziextenzo® is a biosimilar medicine. This means that Ziextenzo® is highly similar to another biological medicine (the reference medicine) that is already authorised in the European Union. The reference medicine for Ziextenzo® is Neulasta®.

**Ziextenzo® solution for injection pre-filled syringe 6 mg/0.6 ml**



- Each pack contains one PFS, containing 6 mg of pegfilgrastim.
- It is supplied as a clear, colourless to slightly yellowish solution for injection.

### Storage

- Ziextenzo® PFS should be stored in a refrigerator (2°C - 8°C). It should not be frozen. Accidental exposure to freezing temperatures for a single period of less than 24 hours does not adversely affect its stability.
- The PFS should be kept in the original packaging in order to protect it from light.
- The PFS may be exposed to room temperature (not above 35°C) for a maximum single period of up to 120 hours. It should be discarded if left at room temperature for longer than 120 hours.

### Dose Administration

- Before use, the solution for injection in Ziextenzo® PFS should be inspected visually for particulate matter. Only a solution that is clear and colourless to slightly yellowish should be injected.
- The PFS should be allowed to reach room temperature for 15-30 minutes before injecting.
- Excessive shaking of the PFS should be avoided as it may aggregate pegfilgrastim, rendering it biologically inactive.
- The patient information leaflet contains a clear diagrammatic guide on how to administer a dose from the PFS.
- The plunger rod must be slowly depressed as far as it will go so that the plunger head is completely between the needle guard wings. The plunger should be pressed fully down while the PFS is held in place for five seconds pushed to ensure that the full dose of pegfilgrastim is delivered.
- The plunger should be kept fully depressed while the patient pulls the needle straight out from the injection site. The patient should then slowly release the plunger and allow the syringe needle guard to automatically cover the exposed needle.

### Similarities between Ziextenzo® PFS and the reference biological medicine (Neulasta® PFS)

- Ziextenzo® PFS and Neulasta® PFS have a shelf life of three years.
- Ziextenzo® PFS and Neulasta® PFS have a safety feature to guard the needle upon delivery of a dose of pegfilgrastim.

### Differences between Ziextenzo® PFS and the reference biological medicine (Neulasta® PFS)

- Ziextenzo® PFS may be exposed to room temperature (not above 35°C) for a maximum single period of up to 120 hours. It should be discarded if left at room temperature for longer than 120 hours. Neulasta® PFS may be exposed to room temperature (not above 30°C) for a maximum single period of up to 72 hours.
- Ziextenzo® PFS contains a 29-gauge needle; Neulasta® PFS contains a 27-gauge needle.<sup>1</sup>
- There is no latex in Ziextenzo® PFS or its associated packaging. The needle cover of Neulasta® PFS contains dry natural rubber (a derivative of latex), which may cause allergic reactions.



<sup>1</sup> A higher needle gauge is indicative of a smaller bore size for the needle, i.e. a thinner needle

## Rowex Limited Patient Support Services

Rowex Limited provide a patient support service to patients who have been prescribed Ziextenzo®. Point of Care Health Services provides this service on behalf of Rowex Limited.

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

- Home visit nurse support: This includes training on the Ziextenzo® administration device and education on the biological medicine.
- Virtual nurse support: Nurse training support can be delivered remotely, if required
- Ongoing nurse support to accommodate individual patient needs
- Provision of a patient information booklet to include a self-injection administration guide
- Access to a patient support phonenumber
- Provision of an approved sharps bin for waste management
- Access to a dedicated website for Ziextenzo®, which provides a variety of educational materials, e.g. patient guide to Ziextenzo®, online tutorial video on how to inject Ziextenzo® and information on neutropenia.

**In order to avail of the patient support services for patients who have been prescribed Ziextenzo®, please contact Point of Care on 01 468 8973 or by emailing [carecoordination@pointofcare.ie](mailto:carecoordination@pointofcare.ie).**

**A Ziextenzo® referral form is also available and upon completion, can be emailed to [carecoordination@pointofcare.ie](mailto:carecoordination@pointofcare.ie) or faxed to 01 6865153.**

In order to obtain demonstration devices and patient support materials for use in clinics, please contact Suzanne Buckley:

- **Email:** [suzanne.buckley@uniphar.com](mailto:suzanne.buckley@uniphar.com)
- **Phone:** 085 8009299

### References:

1. Ziextenzo® 6 mg/0.6 ml solution for injection in pre-filled syringe. Summary of Product Characteristics. Last revised 04/12/2023. Accessed at [www.ema.europa.eu](http://www.ema.europa.eu) on 11/03/2024.