Information for Consumers and Carers
Pharmaceutical Benefits Scheme - Biosimilar PEGFILGRASTIM

The following biosimilar brands of pegfilgrastim are listed on the Pharmaceutical Benefits Scheme (PBS):

<table>
<thead>
<tr>
<th>Brand name</th>
<th>Date of PBS Listing</th>
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<tbody>
<tr>
<td>Ziextenzo®</td>
<td>1 March 2020</td>
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<tr>
<td>Fulphila®</td>
<td>1 April 2020</td>
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<tr>
<td>Pelgraz®</td>
<td>1 August 2020</td>
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These brands have been assessed by the Therapeutic Goods Administration on the basis of comparability and clinical studies to be highly similar to the reference brand, Neulasta®. This means that Ziextenzo®, Fulphila®, Pelgraz® and Neulasta® provide the same health outcomes and are as safe and effective as each other.

Medicines listed on the PBS are subsidised by the Commonwealth of Australia where they are priced above the PBS co-payment amount.

Other brands of pegfilgrastim on the PBS
Two other brands, Ristempa® and Tezmota®, are also available on the PBS. These are provided to the market by the same pharmaceutical company as the reference brand.

Fulphila®, Pelgraz® and Ziextenzo® are considered equally safe and effective as Ristempa® and Tezmota®.

Pegfilgrastim and PBS brand substitution
The independent expert Pharmaceutical Benefits Advisory Committee (PBAC) recommended that Fulphila®, Pelgraz® and Ziextenzo® be listed on the PBS as substitutable with Neulasta®, the reference brand of pegfilgrastim.

When PBS brands are listed as substitutable the pharmacist can dispense any brand, with permission from the patient, unless otherwise directed by the prescriber.

What is pegfilgrastim?
Pegfilgrastim is a biological medicine that is used to treat chemotherapy-induced neutropenia. Your doctor can discuss with you the detailed requirements around prescribing pegfilgrastim under the PBS.

Pegfilgrastim is prescribed by specialists. It is administered in a hospital or clinic and given through an infusion into a vein.

More information about this medicine is available by entering ‘pegfilgrastim’ at the NPS MedicineWise Medicine Finder.
What are biological and biosimilar medicines?
Biological medicines, including biosimilars, contain substances made by living cells or organisms. They are more complex to make than synthetic chemical medicines.

A biosimilar medicine is a highly similar version of a reference biological medicine, which is invariably the first brand to market. Biosimilar medicines are used to treat the same diseases, in the same way, as the reference biological medicines.

Biosimilar medicines have been tested and shown to be as safe and effective as the reference biological medicines.

Who chooses the brand?
In Australia, injections of pegfilgrastim are usually given in a hospital or clinic. The choice of brand generally used in a hospital or clinic may be based on medicine purchasing decisions made by a doctor-led committee. Specific patient requirements will be discussed between a patient and their doctor.

Will I have the same health outcome no matter which brand of pegfilgrastim I use?
Yes. The TGA approved the biosimilars Fulphila®, Pelgraz® and Ziextenzo® because they were determined to be as safe and effective as the reference brand Neulasta® and to provide the same health outcomes.

Why are biosimilar medicines important?
The growing cost of new and innovative medicines, including biological medicines, continues to put pressure on the financial sustainability of the PBS. Eight of the ten most expensive medicines subsidised by the PBS in 2018-19 were biological medicines with a combined cost of $1.87 billion. The cost to Government for pegfilgrastim alone in 2018-19 was $68.8 million. The introduction of biosimilar medicines encourages brand competition in the Australian market. This will lead to a reduction in the cost of biological medicines, improving the Government’s capacity to subsidise access to new and innovative treatments for seriously ill patients.

Where can I find more Information?
The biosimilars page on the Australian Government Department of Health website
The biosimilars regulation page on the Therapeutic Goods Administration website
The PBAC Public Summary Document for Fulphila® on the PBAC webpage of the PBS website.
The PBAC Public Summary Document for Pelgraz® on the PBAC webpage of the PBS website.
The PBAC Public Summary Document for Ziextenzo® on the PBAC webpage of the PBS website.
The Biosimilar Education Hub (for consumers and carers)