Australian Government
Department of Health

Pharmaceutical Benefits Scheme
Biosimilar PEGFILGRASTIM

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

Brand name	Date listed on PBS
Ziextenzo®	1 March 2020
Pelgraz®	1 August 2020

These brands are listed under the Section 100 Highly Specialised Drugs Program (HSD Program).

Other brands of pegfilgrastim on the PBS

Two other brands, Ristempa® and Tezmota®, are also available on the PBS. These are co-marketed with the reference brand by the same pharmaceutical company. The brands Ristempa and Tezmota are not considered to be biosimilar brands.

Pelgraz and Ziextenzo are considered equally safe and effective as the reference brand Neulasta® and the co-marketed brands Ristempa and Tezmota.

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.

How is biosimilarity determined?

Biosimilar medicines are designed and engineered to be as similar as possible to the reference biological medicine. There may be minor differences (known as molecular microheterogeneity) due to natural variability and the more complex manufacturing processes required for biological medicines. Importantly, these minor differences do not affect the safety, quality or effectiveness of the biosimilar medicine.

For a biosimilar medicine to be approved by the Therapeutic Goods Administration (TGA), the structural variability of the biosimilar medicine and the reference biological medicine, and all critical quality attributes (i.e. those important for the function of the molecule) must be highly similar. There must also be no clinically meaningful differences identified in clinical studies comparing the biosimilar and reference products.

Pelgraz and Ziextenzo have been assessed by the TGA on the basis of comparability and clinical studies to be highly similar to the reference brand, Neulasta. This means that Pelgraz and Ziextenzo provide the same health outcomes and are as safe and effective as Neulasta.

What is pegfilgrastim?

Pegfilgrastim is a biological medicine used to treat chemotherapy-induced neutropenia.

More information about this medicine is available by entering 'pegfilgrastim' at the NPS MedicineWise Medicine Finder.

Can PBS brands of pegfilgrastim be substituted?

The Pharmaceutical Benefits Advisory Committee (PBAC), an independent, expert advisory body, recommended that Pelgraz and Ziextenzo be listed on the PBS as substitutable biosimilars of Neulasta. The brands are marked in the Schedule with an 'a'-flag.

When PBS brands are listed as substitutable with each other, the pharmacist may dispense any brand, provided the prescriber has not indicated 'brand substitution not permitted' on the prescription, and they have permission from the patient.

What are the PBS restrictions for pegfilgrastim?

All brands of pegfilgrastim are currently available as Authority Required (STREAMLINED) in both public and private hospitals.

The Schedule of Pharmaceutical Benefits, available online, in PDF and in prescribing software, contains the details of initial, first continuing and subsequent continuing treatment phase criteria and eligibility details. Note that over time PBS listing details may change – please consult the Schedule for current information.

Do biosimilar uptake drivers apply to pegfilgrastim?

The Government has implemented policies to encourage greater use of biosimilar brands.

The PBS listings for pegfilgrastim were changed from 1 March 2020. To encourage uptake an administrative Note has been added for prescribers in the Schedule. The Note is applicable for initial treatment with pegfilgrastim:

> *Note*
>
> *Biosimilar prescribing policy*
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> *Prescribing of the biosimilar brand Pelgraz and Ziextenzo is encouraged for treatment naïve patients. Encouraging biosimilar prescribing for treatment naïve patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments.*

Further information about the biosimilar uptake drivers is available on the PBS website.

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 2020-21 were biological medicines with a combined cost of $2.41 billion. The introduction of biosimilars on the PBS can help relieve this pressure.

How can greater use of biosimilars benefit the PBS?

The introduction of brand competition into the market leads to lower PBS prices, due to Price Disclosure and other statutory price reductions to PBS medicines. Under Price Disclosure arrangements the PBS subsidy is adjusted twice a year to reflect average market prices. As these become lower through competition, the prices of medicines that have at least one other brand on the PBS can be reduced. A price reduction only occurs if the weighted average discounting across all brands of a drug is greater than set percentages.

Savings from statutory price reductions to PBS medicines are being re-invested in the PBS, ensuring all Australians continue to have the earliest possible access to new medicines. All Australian patients benefit from rapid, equitable and sustainable access to the most effective medicines through the PBS.

Detailed information about PBS pricing, including Price Disclosure, is available on the PBS website.

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 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 (Generic and Biosimilar Medicines Association Education website funded by the Commonwealth)

Further information for healthcare professionals regarding the use of PBS authorities and claiming of PBS benefits is available at the Services Australia website, using the search terms ‘PBS Authorities’ and ‘Claim a benefit – Medicare benefits for health professionals’.