



Australian Government

Department of Health

Information for Healthcare Professionals Pharmaceutical Benefits Scheme - Biosimilar PEGFILGRASTIM

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

Brand name	Date of PBS Listing
Ziextenzo [®]	1 March 2020
Fulphila [®]	1 April 2020
Pelgraz [®]	1 August 2020

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 Fulphila[®], Neulasta[®], Pelgraz[®] and Ziextenzo[®] provide the same health outcomes and are as safe and effective as each other.

A summary of the pegfilgrastim PBS listings for each indication is provided in the **table below**.

Refer to the Schedule of Pharmaceutical Benefits, available [online](#), in [PDF](#) and in prescribing software, for detailed information on the PBS prescribing restrictions.

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 considered to be 're-branded products' or 'co-marketed' brands, rather than biosimilar brands.

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

Prescriber choice and brand substitution

The Pharmaceutical Benefits Advisory Committee (PBAC) recommended that Fulphila[®], Pelgraz[®] and Ziextenzo[®] be listed on the PBS as substitutable biosimilars of Neulasta[®], the reference brand of pegfilgrastim.

Prescribers retain, in consultation with their patient, the choice of which brand to prescribe. 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', and they have permission from the patient.

What is pegfilgrastim?

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

What is a biological medicine?

Biological medicines, including biosimilars, contain active substances derived from living cells or organisms. Compared to synthetic chemical medicines, biological medicines are more

complex and have an inherent degree of minor variability in the production process. This means no two batches of a biological medicine (even from the same manufacturer) are ever exactly the same.

What is a biosimilar medicine?

Biosimilar medicines are highly similar versions of an already registered reference brand of a biological medicine.

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, 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.

Who chooses whether the biosimilar brand is used?

In Australia, subcutaneous injections of pegfilgrastim are usually administered 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 clinician-led committee. Specific patient requirements will remain for discussion between a patient and treating clinician.

Prescribers are encouraged to discuss biosimilar medicines with patients. See "[How do I talk to patients about biosimilar medicines?](#)" in the 'Information for health care professionals' FAQs on the Australian Government Department of Health website.

Why are biosimilar medicines important?

The PBS is a key element of Australia's National Medicines Policy, which aims to deliver timely access to medicines at a cost that individuals and the community can afford.

Increasing costs associated with very expensive new health technologies, and the increasing prevalence of chronic conditions, is putting pressure on the 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.

Increasing the use of biosimilar medicines is expected to deliver significant reductions in the cost of the PBS, due to price competition in the market. This can improve the Government's capacity to fund expanded access to biological medicines as they become more affordable, and reduce the risk of medicine shortages.

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](#)

TABLES

For Authority Required (Streamlined) listings, prescribers need to request authority approval from Services Australia (formerly the Department of Human Services) to prescribe increased quantity and/or repeats in line with the PBS restriction.

Pegfilgrastim Highly Specialised Drugs (Public) PBS Listings Summary

The following items are **Authority Required (STREAMLINED)**.

Form / Strength	Brand	Indication	Authority Level/Code	PBS Item Code for Claiming
6mg/0.6 mL injection, injection, 0.6 mL syringe	Fulphila ^a Neulasta ^a Pelgraz ^a Ristempa ^a Tezmota ^a Ziextenzo ^a	Chemotherapy-induced neutropenia	Streamlined (7822, 7843)	9514R

Pegfilgrastim Highly Specialised Drugs (Private) PBS Listings Summary

The following items are **Authority Required (STREAMLINED)**.

Form / Strength	Brand	Indication	Authority Level/Code	PBS Item Code for Claiming
6mg/0.6 mL injection, injection, 0.6 mL syringe	Fulphila ^a Neulasta ^a Pelgraz ^a Ristempa ^a Tezmota ^a Ziextenzo ^a	Chemotherapy-induced neutropenia	Streamlined (9235, 9303)	6363X

'a' – indicates 'a'-flagged (PBS brand equivalence).

For more detailed information on prescribing conditions, please refer to the *Schedule of Pharmaceutical Benefits*.

Note that the brands Tezmota[®] and Ristempa[®] are co-marketed brands of the reference brand, and are not biosimilar brands.