



# Pharmaceutical Benefits Scheme – Biosimilar Filgrastim

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

Brand name	Date listed on PBS
Nivestim®	1 April 2011
Zarzio®	1 September 2013

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

## 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.

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

Nivestim was approved by the TGA and listed on the PBS prior to the TGA's updated biosimilar registration process in December 2015. It was approved on the basis of the

European Union Guideline for Similar Biological Medicinal Products adopted by the TGA. Zarzio was also subsequently approved on this basis.

## Neupogen delisting

Neupogen was removed from the PBS on 1 December 2023 at the request of the sponsor. Following de-listing, PBS Supply Only arrangements are applied to Neupogen to enable repeat dispensing of some forms and strengths for a limited time.

## What is filgrastim?

Filgrastim is a biological medicine in the granulocyte colony stimulating agents (G-CSF) class and acts to stimulate bone marrow to produce white blood cells. It is used to treat neutropenia resulting from reduced white blood cell counts in patients undergoing chemotherapy or receiving bone marrow transplants. It is also used to stimulate the release of stem cells in the blood for subsequent stem cell collection and transplantation.

More information about this medicine is available by entering 'filgrastim' at the [NPS MedicineWise Medicine Finder](#).

## Can PBS brands of filgrastim be substituted?

The Pharmaceutical Benefits Advisory Committee (PBAC), an independent, expert advisory body to the Australian Government, recommended that from 1 October 2019 Nivestim and Zarzio be listed on the PBS as substitutable biosimilars of Neupogen for all approved indications. Following the removal of Neupogen from the PBS, Nivestim and Zarzio remain 'a'-flagged in the Schedule. When PBS brands are 'a'-flagged with each other, the pharmacist may dispense any of these brands, in consultation with the patient and provided the prescriber has not indicated 'brand substitution not permitted' on the prescription.

Substitution is also permitted between formulations when the total amount of drug is the same, and a note has been placed in the Schedule of Pharmaceutical Benefits listing to indicate that substitution is permissible.

## Authority requirements for filgrastim

Authority levels for HSD Program – Private and Public Hospital (s100) PBS listings of filgrastim are [Authority Required \(STREAMLINED\)](#).

Read the Schedule of Pharmaceutical Benefits for the complete restrictions for [filgrastim](#). The Schedule is also available via the [PBS publications page](#). Prescribing software also contains eligibility details. Over time PBS listing details may change – please consult the Schedule for current information.

## Why are biosimilar medicines important?

The PBS subsidises a range of biological medicines to treat cancers, immunological and degenerative disorders, which significantly affect the quality of life for affected individuals. These are generally innovative treatments and their increasing cost and utilisation across a range of disease indications continue to put pressure on the PBS. In 2022-23, biological medicines represented six of the ten PBS medicines which attracted the most Government

subsidy, with a combined cost of \$2.25 billion. Biosimilar prescribing can help relieve this pressure.

## How can greater use of biosimilars benefit the PBS?

Brand competition can lead 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 timely, 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

For more information, read:

- Department of Health and Aged Care website [About medicines](#) page.
- Therapeutic Goods Administration website [biosimilars medicines regulation](#).
- PBS website – PBAC Public summary document for [Nivestim](#).
- The [Biosimilar Education Hub](#) (Generic and Biosimilar Medicines Association Education website, originally funded by the Australian Government).

Further information for healthcare professionals regarding the use of [PBS Authorities](#) and [claiming of PBS benefits](#) is available at the [Services Australia](#) website.