MEDICATION SAFETY COMMUNICATION

Information for health professionals in NSW public health organisations

Filgrastim (Neupogen®) injection products – 9 November 2023	
Details of affected product(s)	Filgrastim (Neupogen) 300 microg/1 mL injection vial – ARTG ID: 53579 Filgrastim (Neupogen) 480 microg/1.6 mL injection vial – ARTG ID: 53577 Filgrastim (Neupogen) 300 microg/0.5 mL injection syringe – ARTG ID:53580 Filgrastim (Neupogen) 480 microg/0.5 mL injection syringe – ARTG ID: 53581
Reason for communication	Discontinuation
Supply impact dates	Ongoing

Main indications and use

Filgrastim is a granulocyte colony-stimulating factor (G-CSF) which acts by stimulating the production and differentiation of neutrophils, from blood precursor cells. It is indicated for use in:

- Reduction of the duration and clinical sequelae resulting from neutropenia in patients:
  - with haematological malignancy receiving myelosuppressive chemotherapy
  - with haematological malignancy receiving induction, maintenance and consolidation chemotherapy
  - receiving myeloablative chemotherapy followed by bone marrow transplantation
- Mobilisation of stem cells in patients who require subsequent autologous infusion after myeloablative or myelosuppressive treatment
- Mobilisation of stem cells in healthy donors for use in allogeneic transplantation
- Severe chronic neutropenia
- Drug-induced neutropenia in HIV patients.

Situation

In June 2023, the Therapeutic Goods Administration (TGA) announced the deletion of the following products from the Australian Register of Therapeutic Goods:

- Filgrastim (Neupogen) 300 microg/1 mL injection vial (ARTG ID: 53579) from 1 March 2024
- Filgrastim (Neupogen) 480 microg/1.6 mL injection vial (ARTG ID: 53577) from 1 October 2023
- Filgrastim (Neupogen) 300 microg/0.5 mL injection syringe (ARTG ID:53580) from 1 April 2024
- Filgrastim (Neupogen) 480 microg/0.5 mL injection syringe (ARTG ID: 53581) from 1 April 2024.

The product manufacturer has advised that there will be a decrease in supply of these products until their remaining stock is exhausted.

Alternative agents

Alternative brands of filgrastim biosimilar products such as Nivestim® and Zarzio® are unaffected and remain available.

Precautions, safety issues and other considerations associated with alternatives

Concerns have previously been raised regarding the use of filgrastim biosimilar products for stem cell mobilisation in normal donors. However, the Department of Health and Aging has listed Nivestim and Zarzio as '*substitutable biosimilars of Neupogen for all approved indications*'.

A review of the literature has demonstrated that the efficacy and safety of Nivestim and Zarzio is comparable with Neupogen products. The Agency for Clinical Innovation (ACI) Blood and Marrow Transplant and Cellular Therapies (BMT+CT) Network has advised that Nivestim has been utilised, particularly by autologous centres. However, the use of Zarzio has been limited on a national scale.

It is recommended that donors mobilised with filgrastim biosimilar products are closely monitored and any issues with efficacy or safety are reported via local incident management systems e.g., ims+ and back to the TGA, ACI BMT+CT Network and the CEC Medication Safety team.

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Impacts of this communication on\clinical practice

Actions to address the discontinuation of Neupogen products should be coordinated and implemented by the local Drug and Therapeutics Committee in consultation with the relevant clinicians. Alternative filgrastim products are available and can be utilised by facilities after consideration of the above precautions and safety issues.

Associated regulatory or policy references

PD2022_032 Medication Handling
PD2019_019 Coordination of responses to urgent system-level medicine or medical device issues

Key contacts

Clinical Excellence Commission (Medication Safety) – CEC-MedicationSafety@health.nsw.gov.au
HealthShare NSW (Category Manager – Strategic Procurement) – Noman.Masood@health.nsw.gov.au

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