



Australian Government

Department of Health

Factsheet for Consumers and Carers Pharmaceutical Benefits Scheme – New Biosimilar INSULIN GLARGINE

Semglee[®] is a new brand of insulin glargine listed on the Pharmaceutical Benefits Scheme (PBS) on 1 October 2019. It is a biosimilar to the reference biological medicine Lantus[®], and is marked as equivalent (a'a-flagged) in the PBS to the Lantus SoloStar[®] brand. These brands contain the active ingredient insulin glargine and have been assessed by the Therapeutic Goods Administration (TGA) to be highly similar. Semglee[®] provides the same health outcome and is as safe and effective as Lantus[®], and uses the same pre-filled disposable pen device as Lantus SoloStar[®].

Medicines on the PBS are subsidised by the Australian Government.

What is insulin glargine?

Insulin glargine is a biological medicine that is used to treat diabetes mellitus. It is a long-acting form of insulin. Your doctor can discuss with you the detailed requirements around prescribing PBS subsidised insulin glargine.

More information about this medicine is available by entering 'insulin glargine' 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 chemical based medicines.

A biosimilar medicine is a highly similar version of a reference biological medicine, which is 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.

Insulin glargine and PBS brand substitution

The independent expert Pharmaceutical Benefits Advisory Committee (PBAC) recommended that Semglee[®] be listed on the PBS as substitutable biosimilar of the Lantus SoloStar[®] brand of insulin glargine, which is related to the reference brand Lantus[®].

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

Who chooses the brand?

The choice of which brand of insulin glargine to use is made by the doctor in consultation with the patient. Specific patient requirements will remain for discussion between a patient and their doctor.

Will I have the same health outcome no matter which brand of insulin glargine I use?

Yes. The TGA approved Semglee[®] as a biosimilar of Lantus[®] because it was determined to be as safe and effective as Lantus[®] and provides 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. Seven of the ten most expensive medicines subsidised by the PBS in 2017-18 were biological medicines with a combined cost of \$1.53 billion. The introduction of biosimilar medicines encourages brand competition in the Australian market. This will lead to a reduction in the cost of biological medicines, ensuring the government can continue 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 Semglee[®] on the [PBS website](#)