



Australian Government

Department of Health

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

Semglee[®] is a brand of insulin glargine listed on the Pharmaceutical Benefits Scheme (PBS) from 1 October 2019. It was assessed as biosimilar to the reference brand of insulin glargine, and is marked as equivalent ('a'-flagged) in the PBS to the other currently listed brand, Optisulin SoloStar[®].

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 Optisulin SoloStar[®].

The insulin glargine brands Lantus Solostar[®] and Lantus[®], which were previously listed on the PBS, are no longer available in Australia and have therefore been de-listed. As a result Semglee[®] is now 'a'-flagged with Optisulin SoloStar[®] only.

Medicines on the PBS are subsidised by the Commonwealth of Australia.

Other brands of insulin glargine on the PBS

Optisulin[®] is another brand available on the PBS in the same strength, but presented as a cartridge rather than a pen device. Another brand, Toujeo SoloStar[®] is also available on the PBS as a higher strength.

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 the first brand to market, which is known as the reference biological medicine. 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 a substitutable biosimilar of the Lantus SoloStar[®] brand. Following removal of the Lantus SoloStar[®] brand from the PBS, Semglee[®] is now considered substitutable with Optisulin SoloStar[®].

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

While Optisulin® is regarded as equivalent, it is not considered substitutable with Semglee® and Optisulin SoloStar®. This is because Semglee® and Optisulin SoloStar® are disposable pen devices, while Optisulin® is a cartridge (for use in a re-usable injection device).

PBS brands which are 'a'-flagged are considered equally safe and effective.

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 the reference brand because it was determined to be as safe and effective, and provided 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. 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 taxpayers for insulin glargine alone in 2018–19 was \$94.4 million. The introduction of biosimilar medicines encourages brand competition in the Australian 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 Semglee® on the [PBS website](#)