



Australian Government

Department of Health

Factsheet for Healthcare Professionals Pharmaceutical Benefits Scheme – Biosimilar INSULIN GLARGINE

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

These brands contain the active ingredient insulin glargine and have been assessed by the Therapeutic Goods Administration (TGA) on the basis of comparability and clinical studies to be highly similar to the Lantus[®] reference brand. This meant that Semglee[®], Optisulin SoloStar[®] and Lantus[®] were considered to provide the same health outcomes and were considered as safe and effective as each other.

From 1 July 2020 the Lantus[®] and Lantus Solostar[®] brands are no longer available in Australia and will therefore no longer be listed on the PBS. As a result Semglee[®] is now 'a'-flagged with Optisulin SoloStar[®] only.

Other brands of insulin glargine on the PBS

Optisulin[®] is another brand that is available on the PBS as 100 units per mL of insulin per injection cartridge. However, it is not considered substitutable with Semglee[®] and Optisulin SoloStar[®]. This is consistent with the advice of the Pharmaceutical Benefits Advisory Committee (PBAC) and is on the basis that the Semglee[®] and Optisulin SoloStar[®] presentations are disposable pen devices, while the Optisulin[®] presentation is a cartridge (for use within a re-usable injection device).

Although Optisulin SoloStar[®] is a pen device, it is currently described in the PBS Schedule as a cartridge. Please see the footnote at the end of this factsheet for further information.

Another brand, Toujeo SoloStar[®] is also available on the PBS, as 300 units per mL.

Prescriber choice and brand substitution

Prescribers retain, in consultation with their patient, the choice of which brand to prescribe. PBS brands which are flagged 'a' are considered equally safe and effective. When PBS brands are listed as substitutable with each other, the pharmacist may dispense any brand, provided they have permission from the patient, and the prescriber has not indicated 'brand substitution not permitted' on the prescription.

What is insulin glargine?

Insulin glargine is a long-acting insulin used to treat diabetes mellitus. It is a recombinant human insulin analogue produced by DNA technology.

Insulin glargine is supplied on the PBS under the General Schedule (s85).

Semglee[®] and Optisulin SoloStar[®] are dosed the same and are available as a pre-filled disposable pen presentation (100 units per mL).

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

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 generally 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 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?

Prescribers retain, in consultation with their patient, the choice of which brand to prescribe. 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 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 taxpayers for insulin glargine alone in 2018–19 was \$94.4 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 Semglee® on the [PBS website](#)

[The Biosimilar Education Hub](#)

TABLE

Insulin glargine (100 units/mL) General Schedule PBS Listings Summary

PBS listing changes following de-listing of Lantus® and Lantus SoloStar® (1 July 2020).

Form / Strength	Brand	Indication	PBS Item Code for Claiming
100 units/mL injection, 5 x 3 mL pen devices	Semglee ^a	Diabetes mellitus	11815W
100 units/mL injection, 5 x 3 mL cartridges	Optisulin Optisulin SoloStar ^a	Diabetes mellitus	9039R

^a – indicates ‘a’-flagged (PBS brand equivalence)

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

Note: Australian Medicines Terminology (AMT) is used wherever possible to describe products listed in the PBS Schedule. Optisulin Solostar® was previously described in AMT as a cartridge but is now described as a pen device. It is not currently possible to amend the PBS description without putting patient access at risk, however the Department of Health is working with vendors of prescribing and dispensing software to implement a solution that will allow the PBS description to be reconciled with AMT by the end of 2020.