



Australian Government

Department of Health

**Information for Consumers and Carers
Pharmaceutical Benefits Scheme – Listing Changes for Biosimilar RITUXIMAB**

Truxima[®] is a brand of rituximab listed in the Pharmaceutical Benefits Scheme (PBS) Schedule on 1 January 2020 through the Efficient Funding of Chemotherapy (EFC) Program. Further listing changes on 1 February 2020 make this brand also available through the Highly Specialised Drugs (HSD) Program, commonly referred to as 'section 100 HSD'. Truxima[®] is the second biosimilar brand on the PBS, and joins the following brands of rituximab listed in the Schedule:

Brand name	Date listed on PBS	Brand status
MabThera [®]	1 February 1999	Reference
Riximyo [®]	1 October 2019	Biosimilar

From 1 October 2019 the PBS listings for rituximab were amended as a part of Australian Government initiatives to encourage the use of biosimilar brands of biological medicines.

Medicines on the PBS are subsidised by the Australian Government where they are priced above the PBS co-payment amount.

What is rituximab?

Rituximab is a biological medicine that is used to treat severe autoimmune inflammatory diseases such as rheumatoid arthritis and polyangiitis. It is also used to treat the cancers, lymphoma and leukaemia. Your doctor can discuss with you the detailed requirements around prescribing rituximab under the PBS.

Rituximab is prescribed by specialists. It is administered in a hospital or clinic and given through an infusion into a vein.

More information about this medicine is available by entering 'rituximab' 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.

Rituximab and PBS brand substitution

The independent expert Pharmaceutical Benefits Advisory Committee (PBAC) recommended that Riximyo[®] and Truxima[®] be listed on the EFC and HSD Programs as substitutable biosimilars of the MabThera[®] reference brand of rituximab.

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

Who chooses the brand?

In Australia, rituximab infusions are administered in a hospital or clinic. The choice of brand generally used in a hospital or clinic may be based on medicine purchasing decisions made by a clinician-led committee. 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 rituximab I use?

Yes. The TGA approved Riximyo[®] and Truxima[®] as biosimilars of MabThera[®] for use in the EFC and HSD Programs because they were determined to be as safe and effective as MabThera[®] and they provide 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 Government for rituximab alone in 2018-19 was \$103.5 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. It can also 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 Riximyo[®] on the [PBS website](#)

The PBAC Public Summary Document for Truxima[®] on the [PBS website](#)

The [Biosimilar Education Hub](#) (for consumers and carers)