



## **Australian Government**

### **Department of Health**

#### **Factsheet for Consumers and Carers Pharmaceutical Benefits Scheme - Biosimilar ETANERCEPT**

Brenzys<sup>®</sup> is a brand of etanercept that was listed on the Pharmaceutical Benefits Scheme (PBS) on 1 April 2017. It is a biosimilar to the reference biological medicine Enbrel<sup>®</sup>. Both brands contain the active ingredient etanercept and have been assessed by the Therapeutic Goods Administration (TGA) to be highly similar. Brenzys<sup>®</sup> provides the same health outcome and is as safe and effective as Enbrel<sup>®</sup>, offering brand choice for many patients.

#### **What is etanercept?**

Etanercept is a biological medicine that is used to treat a range of inflammatory and autoimmune conditions, including rheumatoid arthritis, ankylosing spondylitis, psoriatic arthritis, chronic plaque psoriasis and juvenile idiopathic arthritis. Your doctor can discuss with you the detailed requirements around prescribing PBS subsidised etanercept.

Etanercept works like a natural protein and when given to a patient, it reduces inflammation and other symptoms of disease.

#### **What are biological and biosimilar medicines?**

Biological medicines, including biosimilars, contain substances made by living cells or organisms. They are generally more complex to make than synthetic chemical 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.

#### **Community Pharmacy Dispensing & PBS brand substitution**

Brenzys<sup>®</sup> was the first biosimilar medicine in Australia to be available through community pharmacy, and it can be self-administered after training.

The dosage for Brenzys<sup>®</sup> is the same as for the reference brand Enbrel<sup>®</sup>: 50mg of etanercept per week. It comes in single-use pre-filled syringes and pre-filled pens, and is administered via subcutaneous (SC) injection.

The independent expert Pharmaceutical Benefits Advisory Committee (PBAC) recommended that Brenzys<sup>®</sup> be listed on the PBS as a substitutable biosimilar of the Enbrel<sup>®</sup> brand of etanercept. This means the two brands of etanercept can be substituted by the pharmacist in consultation with the patient. This recommendation was based on individual consideration of the evidence for Brenzys<sup>®</sup>.

## **Who chooses whether the biosimilar medicine or the reference biological medicine is used?**

It is up to you and your doctor to choose which biological medicine to use. You should discuss with your doctor which medicine is right for you.

Your doctor may decide to prescribe a particular brand of medicine. Your pharmacist might offer you the choice of brands – choosing a biosimilar brand is likely to contribute to competition that can drive the price of medicines down. However, your doctor can tick a box on the script to say that brand substitution is not permitted, if they think you should only take a particular brand.

## **Will I have the same health outcome no matter which brands of etanercept I use?**

Yes. The TGA approved the biosimilar Brenzys<sup>®</sup> because it was determined to be as safe and effective as the reference brand Enbrel<sup>®</sup> 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. 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 etanercept alone in 2018–19 was \$105.7 million. The introduction of biosimilar medicines encourages brand competition in the Australian market. This will lead to a reduction in the cost of biological medicines, improving the Government's capacity to subsidise access to new and innovative treatments for seriously ill patients.

## **More Information is available on**

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 Brenzys<sup>®</sup> on the [PBS website](#)

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