



Factsheet for Consumers and Carers

Biosimilar etanercept on the Pharmaceutical Benefits Scheme

Listing of etanercept (Brenzys®) on the PBS from 1 April 2017

Brenzys® is a new brand on the Pharmaceutical Benefits Scheme (PBS) from 1 April 2017. It is a biosimilar to the reference biological medicine Enbrel®. Both brands contain the active ingredient etanercept and have been assessed by the Therapeutic Goods Administration (TGA) to be highly similar. Brenzys® provides the same health outcome and is as safe and effective as Enbrel®, 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 is a biological medicine?

A biological medicine is a medicine that contains substances made by living cells or organisms. It is generally more complex to make than regular chemical based medicines.

What is a biosimilar medicine?

A biosimilar medicine is a highly similar version of a reference biological medicine which is the first brand to market.

Biosimilar medicines are not referred to as generic medicines (although like generics they are competitor brands).

This is because the processes that produce biological medicines are naturally variable. No two batches of biological medicines are ever exactly the same (even from the same manufacturer).

Biosimilar medicines are used to treat the same diseases, in the same way, as the reference biological medicines. They have been tested and shown to be as safe and effective as the reference biological medicines. Australians have been using other biosimilar medicines for more than 10 years.

Community Pharmacy Dispensing & PBS brand substitution

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

The dosage for Brenzys® is the same as for the reference brand Enbrel®, 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® be listed on the PBS as a substitutable biosimilar of the Enbrel® brand of etanercept. This means the two brands of etanercept can be substituted by the pharmacist in consultation with the patient, like with generic brands. This recommendation was based on individual consideration of the evidence for Brenzys®.



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

Yes. The two brands are highly similar and can be substituted. The TGA approved Brenzys[®] as a biosimilar of Enbrel[®] because they determined it to be as safe and effective as Enbrel[®] and it provides the same health outcomes. The PBAC considered that the evidence showed that changing from Enbrel[®] to Brenzys[®] did not affect the clinical outcome for the patient.

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.

Six of the ten most expensive medicines subsidised by the PBS in 2015-16 were biological medicines with a combined cost of \$1.28 billion. Without taxpayer subsidy, these medicines can cost a patient between \$400 - \$1700 per treatment. However when listed for subsidy on the PBS, the maximum a patient pays per script in 2017 is \$38.80, with the government paying the difference. Concessional patients pay \$6.30, or nil if they have reached their PBS safety net.

Biosimilar medicines provide an opportunity to reduce the cost to Government of subsidising biological medicines based on price competition in the market when different brands are used. Lower costs for these very expensive biological medicines will help the Government to pay for other expensive health treatments in the future.

Biosimilar medicines also give patients access to more brand options and can reduce the risk of medicine shortages due to less reliance on single brands.

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

If this box is ticked, by law the pharmacist cannot dispense a brand other than that prescribed.

Where can I find more information?

Australian Government Department of Health: www.health.gov.au/biosimilars

Therapeutic Goods Administration: www.tga.gov.au/publication/evaluation-biosimilars

The PBAC Public Summary Document for Brenzys[®]: www.pbs.gov.au/info/industry/listing/elements/pbac-meetings/psd/pbac-public-summary-documents-july-2016

