



Lupin Group Company

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Dear Pharmacist

**Notification of PBS listing – Nepexto® (etanercept) solution for injection auto-injector**

<b>Distributor:</b>	Generic Health Pty Ltd
<b>Generic Name:</b>	Etanercept
<b>Trade Name:</b>	Nepexto®
<b>Reference Product:</b>	Enbrel®
<b>Strength &amp; AUST R Number:</b>	50 mg/1 mL Auto-injector (AUST R 386938)

**INDICATIONS:**

Nepexto® is indicated for the treatment of:<sup>1</sup>

**Adults**

- **Rheumatoid Arthritis**
  - Active, adult rheumatoid arthritis (RA) in patients who have had inadequate response to one or more disease-modifying antirheumatic drugs (DMARDs). Nepexto® can be used in combination with methotrexate.
  - Severe, active rheumatoid arthritis in adults to slow progression of disease-associated structural damage in patients at high risk of erosive disease.
- **Psoriatic Arthritis**

The signs and symptoms of active and progressive psoriatic arthritis in adults, when the response to previous disease-modifying antirheumatic therapy has been inadequate. Etanercept has been shown to reduce the rate of progression of joint damage as measured by X-ray and to improve physical function.
- **Plaque Psoriasis**

Adult patients with moderate to severe chronic plaque psoriasis, who are candidates for phototherapy or systemic therapy.
- **Ankylosing Spondylitis**

The signs and symptoms of active ankylosing spondylitis in adults.
- **Non-Radiographic Axial Spondyloarthritis**

Treatment of adults with active\* non-radiographic axial spondyloarthritis with objective signs of inflammation as indicated by elevated C-reactive protein (CRP) and/or MRI change who have had an inadequate response to non-steroidal anti-inflammatory drugs (NSAIDs).

\* Active disease is defined as a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score of ≥4.

## **Children and Adolescents**

Children and adolescents weighing less than 62.5 kg should not receive Nepexto®. These patients should be accurately dosed on a mg/kg basis with other etanercept products.

- **Juvenile Idiopathic Arthritis**

- Active polyarthritis (rheumatoid factor positive or negative) in children and adolescents, aged 2 to 17 years, who have had an inadequate response to one or more DMARDs.
- Active extended oligoarthritis in children and adolescents, aged 2 to 17 years, who have had an inadequate response to, or who have proved intolerant to, methotrexate.
- Active enthesitis-related arthritis in adolescents, aged 12 to 17 years, who have had an inadequate response to, or who have proved intolerant to, conventional therapy.
- Active psoriatic arthritis in adolescents, aged 12 to 17 years, who have had an inadequate response to, or who have proved intolerant to, methotrexate.
- Etanercept has not been studied in children aged less than 2 years.

- **Paediatric Plaque Psoriasis**

Chronic, severe plaque psoriasis in children and adolescents from 4 to 17 years, who are inadequately controlled by, or are intolerant to, other systemic therapies or phototherapies. Duration of therapy to be no longer than 24 weeks and treatment to be ceased after 12 weeks if a significant Psoriasis Area and Severity Index (PASI) response is not achieved.

## **PBS LISTING:**

**PBS information: Authority Required (STREAMLINED)**

**PBS Codes: 11198J ; 11201M ; 11202N ; 11215G ; 11218K ; 11221N ; 11222P ; 13319B ; 13326J ; 13687J ; 13697X ; 13708L ; 13774Y ; 1964J ; 3447K ; 3450N ; 5735W ; 9455P ; 9456Q ; 9457R ; 9458T ; 9459W ; 9460X ; 9461Y ; 9462B ; 9641K ; 14852Q**

Refer to [www.pbs.gov.au](http://www.pbs.gov.au) for full information

Generic Health Pty Ltd is pleased to advise you that Nepexto® has been listed on the Pharmaceutical Benefits Scheme (PBS) as at 1 July 2025.

For further information, please refer to the latest Product Information and Consumer Medicine Information available on the TGA website,

<https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/PICMI?OpenForm&t=&q=nepexto&r=/>

Should you have any questions, please refer to the contact details below.

<b>Customer Service Team</b>	Phone: 03 9809 7900, Option 1 Email: <a href="mailto:customer.service@generichealth.com.au">customer.service@generichealth.com.au</a>
<b>Medical Information Team</b>	Phone: 03 9809 7900, Option 2 Email: <a href="mailto:ghinfo@generichealth.com.au">ghinfo@generichealth.com.au</a>
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Yours sincerely,

**Medical Information Team  
Generic Health Pty Ltd**

Date prepared: 01/07/2025

Reference 1: Product Information Nepexto® (etanercept) solution for injection. Available online at <https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/pdf?OpenAgent&id=CP-2024-PI-02948-1&d=20250707172310101>