NEPEXTO® SOLUTION FOR INJECTION IN A PRE-FILLED SYRINGE

Etanercept (25mg, 50mg)

What is in this leaflet

What Nepexto is used for

Nepexto is a biosimilar product based on reference product, Enbrel.

Nepexto is a biological medicine which is made by living organisms. The medicine mimics substances produced by your body.

Nepexto is used to treat:

- Moderately to severely active rheumatoid arthritis (RA). It is a long-lasting inflammation of the joints. Nepexto can be used alone or with a medicine called methotrexate.
- Active polyarticular juvenile idiopathic arthritis in children aged 2 years and older who have had an inadequate response or not tolerant to methotrexate. Polyarticular juvenile idiopathic arthritis is inflammation of many joints of unknown cause seen in children.
- Active psoriatic arthritis. Psoriatic arthritis is mainly inflammation of joints associated with a skin disease called psoriasis which presents as scales or flakes. Nepexto can be used alone or with methotrexate.
- Active axial spondyloarthritis which includes ankylosing spondylitis and non-radiographic axial spondyloarthritis who have had an inadequate response to nonsteroidal anti-inflammatory drugs (NSAIDs). It is a long-lasting inflammation of joints involving the spine and other joints which connects it to the hip bone.
- Moderate to severe plaque psoriasis in adults or long-lasting severe plaque psoriasis in children 6 years and older who were not able to tolerate or have not benefited from taking other treatments such as cyclosporin, methotrexate or psoralen and ultraviolet-A light (PUVA).

How Nepexto works

Nepexto is a human fusion protein that blocks the activity of another protein [tumour necrosis factor (TNF)] in the body that causes inflammation, which in turn reduces inflammation and damage to your joints.

Before you use Nepexto

- *When you must not use it*

Do not take Nepexto if you:

- are allergic to etanercept or to any other ingredients of this medicine (listed in Product Description)
- have sepsis (a life-threatening condition as a response to any infection, causing injury to its own tissue and organs) or at risk of developing sepsis.
- have active infection or long-lasting or localized infection.
- have blood vessel disorder called Wegener's granulomatosis.

Pregnancy and lactation

Do not take Nepexto if you are pregnant, trying to get pregnant or think you may be pregnant. You should use an appropriate birth control method to avoid becoming pregnant during Nepexto therapy and for 3 weeks after stopping Nepexto therapy.

Nepexto should only be used during pregnancy if clearly needed. Your doctor will decide if Nepexto is suitable to be used for you.

Do not take Nepexto if you are breast-feeding. Ask your doctor or pharmacist for advice before taking any medicine. Your doctor should decide if you should stop breastfeeding or stop Nepexto therapy.

- *Before you start use it*

Tell your doctor if you:

- Had recurring infections, chronic infections, or underlying conditions which may predispose you to infections, including serious infections such as sepsis and tuberculosis (TB) or if you have signs and symptoms of an infection such as fever, sweats or chills, cough or flu-like symptoms. Before starting treatment with Nepexto, your doctor should evaluate and treat you for any infections and tuberculosis (active/latent). If you have latent TB infection, preventive treatment should be given prior to treatment with Nepexto.
- Have or have had liver problems including previous or current infection with hepatitis B virus and hepatitis C virus and moderate to severe alcoholic hepatitis (inflammation of the liver).
- Have risk of lymphoma or other types of cancer or skin cancers.
- Have diabetes, your doctor may reduce the dosage of your diabetic medicines.
- Have reduced number of any type of blood cells in your body.
- Have recently been vaccinated. Children should be brought up to date with their immunization before starting treatment with Nepexto.
- Have or have had any neurological disorders including multiple sclerosis and/or Guillain-Barré syndrome (a disease where in the insulation covers of nerve cells are damaged). Your doctor should perform a neurological assessment if you have, have had or are at increased risk of developing demyelinating disease.
- Have a reduced pumping activity of the heart known as congestive heart failure. Nepexto may worsen your heart failure.

- *Taking other medicines*

Using Nepexto may affect the way some medications work and likewise, their use together may also result in serious side effects. Tell your doctor if you are taking:
• anakinra
• abatacept
• sulfasalazine
• other immunosuppressants
• diabetic medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop.

How to use Nepexto

- *How much to use*

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

Rheumatoid Arthritis, Psoriatic Arthritis, Ankylosing Spondyloarthritis and Non-radiographic Axial Spondyloarthritis
In adults (18-64 years), the recommended dose is 25mg twice weekly or 50mg once weekly.

Plaque psoriasis
In adults (18-64 years), the recommended dose is 50mg once weekly. Alternatively, 50m given twice weekly may be used for up to 12 weeks followed, if necessary, by a dose of 50 mg once weekly. Treatment with Nepexto should continue until remission is achieved, for up to 24 weeks. Continuous therapy beyond 24 weeks may be appropriate for some adult patients.

Treatment is usually stopped if there is no response after 12 weeks of treatment. If re-treatment with Nepexto is indicated, the same guidance on treatment duration should be followed. The dose should be 25 mg twice weekly or 50 mg once weekly.

Polyarticular juvenile idiopathis arthritis
In children, the recommended dose is 0.4mg/kg (up to maximum of 25mg per dose) given twice weekly as a subcutaneous injection with an interval of 3-4 days between doses. Treatment is usually stopped if no response after 4 months.

Pediatric plaque psoriasis
In children 6 years and above, the recommended dose is 0.8mg/kg (up to maximum of 50mg per dose) given once weekly for up to 24 weeks. Treatment is usually stopped if no response after 12 weeks. If re-treatment with Nepexto is indicated, the same guidance on treatment dosage and duration should be followed.

- *When to use it*

Use as directed by your doctor or pharmacist.

- *How long to use it*

Continue taking Nepexto for as long as your doctor recommends.

- *If you forget to use it*

Consult your doctor or pharmacist on what you should do if you forget to use it.

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

- *If you use too much (overdose)*

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are using it

- *Things you must do*

Tell your doctor if you:
• experience any signs and symptoms of an infection (fever, chills).
• Develop any cancer throughout Nepexto therapy.

Before injection, Nepexto single-use pre-filled syringe should be taken out of the fridge and allowed to reach room temperature (approximately 30 minutes). The solution should not be warmed in any other way. Immediate use is then recommended (minutes). The needle cover should not be removed while allowing the pre-filled syringe to reach room temperature.

Nepexto is a subcutaneous injection. This means that it is injected under your skin. You should inject Nepexto at areas such as your thigh, abdomen or upper arm. Give each new injection at least 3 cm from the previous site of injection.

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are taking Nepexto.

Tell your doctor immediately if you become pregnant while taking this medication.

Avoid receiving live vaccines while taking Nepexto. Some vaccines may not work as well while you are taking Nepexto.

- *Things you must not do*

Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor or pharmacist.

Do not give Nepexto to anyone else, even if they have the same symptoms or condition as you.

- *Things to be careful of*

Driving and using machines

This medicine may affect your ability to drive or use machines. If the tablets make you feel sick, dizzy or tired, or give you a headache, do not drive or use machines and contact your doctor immediately.

Side effects

Like all medicines, Nepexto can cause side effects, although not everybody gets them.

Visit your doctor or pharmacist immediately if you experience any side effects after taking this medicine.

The very common side effects include:
• infection (including upper respiratory tract infection, bronchitis, cystitis, skin infection)
• headache
• injection site reactions (including bleeding, bruising, redness, itching, pain, swelling)

The common side effects include:
• allergic reactions
• itchiness
• rash
• fever

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring visiting the website npra.gov.my [Consumers→ Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of Nepexto
- *Storage*

Keep out of the reach and sight of children.

Store in a refrigerator (2°C - 8°C).

Do not freeze.

Nepexto may be stored at temperatures up to a maximum of 25°C for a single period of up to four weeks; after which, it should not be refrigerated again. Nepexto should be discarded if not used within four weeks of removal from refrigeration.

- *Disposal*

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description
- *What it looks like*

Nepexto solution for injection are available as pre-filled syringes.

Physical appearance: The solution for injection is clear to slightly opalescent, colourless or pale yellow and may contain small translucent or white particles of protein.

- *Ingredients*
  - Active ingredient
    Etanercept

  - Inactive ingredients
    Trisodium citrate dihydrate, Sodium dihydrogen phosphate dihydrate, Glycine, Sucrose, Sodium chloride, Water for Injection

- *MAL number(s):*
  Nepexto prefilled syringe 25mg
  MAL
  Nepexto prefilled syringe 50mg
  MAL

Manufacturer
Lupin Limited (Biotech Division) Gat No.#1156, Village-Ghotawade, Taluka-Mulshi, dist: Pune – 412115.

Product Registration Holder
Mylan Healthcare Sdn Bhd
(a Viatris company)
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