PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

NEPEXTO 25 mg PS solution for injection in pre-filled syringe

NEPEXTO 50 mg PS solution for injection in pre-filled syringe

NEPEXTO 50 mg Prefill Pen solution for injection in pre-filled pen

Etanercept

Contains sugar: sucrose

Read all of this leaflet carefully before you start using NEPEXTO

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- NEPEXTO has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What NEPEXTO is and what it is used for.
2. What you need to know before you use NEPEXTO.
3. How to use NEPEXTO.
4. Possible side effects.
5. How to store NEPEXTO.
6. Contents of the pack and other information.

1. What NEPEXTO is and what it is used for

NEPEXTO contains the active etanercept which is a medicine that is made from two human proteins. It blocks the activity of another protein in the body that causes inflammation. NEPEXTO works by reducing the inflammation associated with certain diseases.

In adults, NEPEXTO can be used for:

- moderate or severe rheumatoid arthritis (long term autoimmune disroders that mainly affects joints);
- psoriatic arthritis (a type of inflammatory arthritis which can affect any joint in the body);
- severe axial spondyloarthritis (a type of chronic inflammatory arthritis involving the spine and/or sacroiliac joints) including ankylosing spondylitis (a type of arthritis that affects the spine);
- moderate or severe psoriasis (raised, red, scaly patches on the skin).

In each case usually when other widely used treatments have not worked well enough or are not suitable for you.

For rheumatoid arthritis, NEPEXTO is usually used in combination with methotrexate, although it may also be used alone if treatment with methotrexate is unsuitable for you. Whether used alone or in combination with methotrexate, NEPEXTO can slow down the damage to your joints caused by the rheumatoid arthritis and improve your ability to do normal daily activities.

For psoriatic arthritis patients with multiple joint involvement, NEPEXTO can improve your ability to do normal daily activities.

For patients with multiple symmetrical painful or swollen joints (e.g., hands, wrists and feet), NEPEXTO can slow down the structural damage to those joints caused by the disease.

NEPEXTO is also prescribed for the treatment of the following diseases in children and adolescents:

- For the following types of juvenile idiopathic arthritis when treatment with methotrexate has not worked well enough or is not suitable for them:
  - Polyarthritis (rheumatoid factor positive or negative) and extended oligoarthritis in patients from the age of 2 years.
  - Psoriatic arthritis in patients from the age of 12 years.
- For enthesitis-related arthritis in patients from the age of 12 years when other widely used treatments have not worked well enough or are not suitable for them.
- Severe psoriasis in patients from the age of 6 years who have had an inadequate response to (or are unable to take) phototherapies or other systemic therapies.

2. What you need to know before you receive NEPEXTO

NEPEXTO should not be administered to you:

- if you are hypersensitive (allergic) to etanercept or any of the other ingredients of NEPEXTO (listed in section 6).
- if you or the child have or are at risk of developing a serious blood infection called sepsis. If you are not sure, please contact your doctor.
- if you or the child have an infection of any kind. If you are not sure, please talk to your doctor.

Warnings and precautions

Special care should be taken with NEPEXTO:

- Allergic reactions: If you or the child experience allergic reactions such as chest

tightness, wheezing, dizziness or rash, do not inject more NEPEXTO, and contact your doctor immediately.

- Infections/surgery: If you or the child develop a new infection, or are about to have any major surgery, your doctor may wish to monitor the treatment with NEPEXTO.
- Infections/diabetes: Tell your doctor if you or the child have a history of recurrent infections or suffer from diabetes or other conditions that increase the risk of infection.
- Infections/monitoring: If you or the child develop symptoms of an infection such as fever, chills or cough, notify your doctor immediately. Your doctor may decide to continue to monitor you or the child for the presence of infections after you or the child stop using NEPEXTO.
- Tuberculosis: As cases of tuberculosis have been reported in patients treated with NEPEXTO, your doctor will check for signs and symptoms of tuberculosis before starting NEPEXTO. This may include a thorough medical history, a chest X-ray and a tuberculin test. The conduct of these tests should be recorded on the Patient Card. It is very important that you tell your doctor if you or the child have ever had tuberculosis, or have been in close contact with someone who has had tuberculosis. If symptoms of tuberculosis (such as persistent cough, weight loss, listlessness, mild fever), or any other infection appear during or after therapy, tell your doctor immediately.
- Hepatitis B: Tell your doctor if you or the child have or have ever had hepatitis B. Your doctor should test for the presence of hepatitis B infection before you or the child begin treatment with NEPEXTO. Treatment with NEPEXTO may result in reactivation of hepatitis B in patients who have previously been infected with the hepatitis B virus. If this occurs, you should stop using NEPEXTO.
- Hepatitis C: Tell your doctor if you or the child have hepatitis C. Your doctor

may wish to monitor the treatment with NEPEXTO in case the infection worsens.

- Blood disorders: Seek medical advice immediately if you or the child have any signs or symptoms such as persistent fever, sore throat, bruising, bleeding or paleness. Such symptoms may point to the existence of potentially life-threatening blood disorders, which may require discontinuation of NEPEXTO.
- Nervous system and eye disorders: Tell your doctor if you or the child have multiple sclerosis, optic neuritis (inflammation of the nerves of the eyes) or transverse myelitis (inflammation of the spinal cord). Your doctor will determine if NEPEXTO is an appropriate treatment.
- Congestive heart failure: Tell your doctor if you or the child have a history of congestive heart failure, because NEPEXTO needs to be used with caution under these circumstances.
- Cancer: Tell your doctor if you have or have ever had lymphoma (a type of blood cancer) or any other cancer before you are given NEPEXTO. Patients with severe rheumatoid arthritis, who have had the disease for a long time, may be at higher than average risk of developing lymphoma. Children and adults using NEPEXTO may have an increased risk of developing lymphoma or another cancer. Some children and teenage patients who have received NEPEXTO or other medicines that work the same way as NEPEXTO have developed cancers, including unusual types, which sometimes resulted in death. Some patients receiving NEPEXTO have developed skin cancers. Tell your doctor if you or the child develop any change in the appearance of the skin or growths on the skin.
- Chickenpox: Tell your doctor if you or the child are exposed to chickenpox when using NEPEXTO. Your doctor will determine if preventive treatment for chickenpox is appropriate.

- Alcohol abuse: NEPEXTO should not be used for the treatment of hepatitis related to alcohol abuse. Please tell your doctor if you or the child in your care have a history of alcohol abuse.
- Wegener's granulomatosis: NEPEXTO is not recommended for the treatment of Wegener's granulomatosis, a rare inflammatory disease. If you or the child in your care have Wegener's granulomatosis, talk to your doctor.
- Anti-diabetic medicines: Tell your doctor if you or the child have diabetes or are taking medicines to treat diabetes. Your doctor may decide if you or the child need less anti-diabetic medicine while using NEPEXTO.

Children and adolescents

- Vaccinations: If possible, children should be up to date with all vaccinations before using NEPEXTO. Some vaccines, such as oral polio vaccine, should not be given while using NEPEXTO. Please consult your doctor before you or the child receive any vaccines.
- Inflammatory bowel disease (IBD): There have been cases of IBD in patients with juvenile idiopathic arthritis (JIA) treated with NEPEXTO. Tell the doctor if the child develops any abdominal cramps and pain, diarrhoea, weight loss or blood in the stool.

Other medicines and NEPEXTO

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

Tell the doctor or pharmacist if you or the child are taking, have recently taken or might take any other medicines (including anakinra, abatacept or sulfasalazine), even those not prescribed by the doctor. You or the child should not use NEPEXTO

with medicines that contain the active substance anakinra or abatacept, medicines used to treat rheumatoid arthritis.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before you receive NEPEXTO.

NEPEXTO should only be used during pregnancy if clearly needed. If you received NEPEXTO during pregnancy, your baby may have a higher risk of getting an infection. It is important that you tell the baby's doctors and other healthcare professionals about the use of NEPEXTO during pregnancy before the baby receives any vaccine (for more information see section 2, "Vaccinations").

Women using NEPEXTO should not breastfeed, since NEPEXTO passes into human breast milk.

Driving and using machines

It is not always possible to predict to what extent NEPEXTO may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which NEPEXTO affects them.

The use of NEPEXTO is not expected to affect the ability to drive or use machines.

NEPEXTO contains sucrose

NEPEXTO contains sucrose which may have an effect on the control of your blood sugar if you have diabetes mellitus.

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking NEPEXTO.

NEPEXTO contains sodium

This medicine contains less than 1 mmol (23 mg) sodium per dose, that is to say, essentially 'sodium-free'.

3. How to receive NEPEXTO

Do not share medicines prescribed for you with any other person.

Always use NEPEXTO exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Dosing for adult patients (aged 18 years or over)

Rheumatoid arthritis, psoriatic arthritis, and axial spondyloarthritis including ankylosing spondylitis:

The usual dose is 25 mg given twice a week or 50 mg once a week as an injection under the skin. However, your doctor may determine an alternative frequency at which to inject NEPEXTO.

Plaque psoriasis

The usual dose is 25 mg twice a week or 50 mg once a week.

Alternatively, 50 mg may be given twice a week for up to 12 weeks, followed by 25 mg twice a week or 50 mg once a week.

Your doctor will decide how long you should take NEPEXTO and whether retreatment is needed based on your response. If NEPEXTO has no effect on your condition after 12 weeks, your doctor may tell you to stop using this medicine.

Children and adolescent:

Use in children and adolescents

The appropriate dose and frequency of dosing for the child or adolescent will depend on body weight and disease. Your doctor will determine the correct dose for the child and will prescribe an appropriate strength of NEPEXTO (25 mg or 50 mg). NEPEXTO is available as 25 mg pre-filled syringe, 50 mg prefilled syringe and 50 mg pre-filled pen. Thus, it is only suitable to administer NEPEXTO to paediatric patients that require a full 25 mg or 50 mg dose.

Patients weighing 62,5 kg or more may be dosed using a fixed-dose pre-filled syringe or pre-filled pen.

For polyarthritis or extended oligoarthritis in patients from the age of 2 years, or enthesitis-related arthritis or psoriatic arthritis in patients from the age of 12 years, the usual dose is 0,4 mg of NEPEXTO per kg bodyweight (up to a maximum of 25 mg) given twice weekly, or 0,8 mg of NEPEXTO per kg of bodyweight (up to a maximum of 50 mg) given once weekly.

For psoriasis in patients from the age of 6 years, the usual dose is 0,8 mg of NEPEXTO per kg bodyweight (up to a maximum of 50 mg) and should be given once weekly. If NEPEXTO has no effect on the child's condition after 12 weeks, your doctor may tell you to stop using this medicine.

The doctor will provide you with detailed directions for preparing and measuring the appropriate dose.

Method and route of administration

NEPEXTO is administered by an injection under the skin (as subcutaneous injections in the thigh, abdomen, or upper arm). Alternate injection sites. New injections should be given at least 3 cm from a previous site. Do NOT inject into areas where the skin is tender, bruised, red, or hard.

Instructions for use for the pre-filled syringe:

This section is divided into the following subsections:

Introduction

Step 1: Setting up for an injection.

Step 2: Choosing an injection site.

Step 3: Injecting the NEPEXTO solution.

Step 4: Disposing of supplies (see section 5.)

The following instructions explain how to prepare and inject NEPEXTO. Read the Instructions for Use before you start using NEPEXTO and each time you get a refill of your prescription. There may be new information.

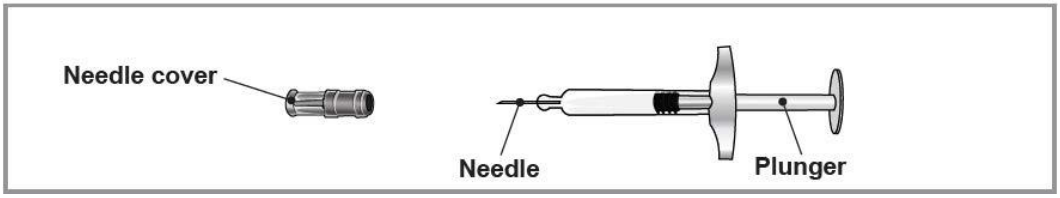
- Do not try to give yourself the injection unless your doctor or nurse has shown you how to give the injection.

The solution should not be mixed with any other medicine before use.

Not included in pack:

- Alcohol swab
- Gauze pad and plaster
- Sharps disposal container

Device Parts



Step 1: Setting up for an injection

Find a, well-lit, clean flat surface and gather all the equipment you need.

1. Take the carton containing the pre-filled syringes out of the refrigerator and place it on a flat work surface. Remove one pre-filled syringe and place it on your work surface. Do not shake the pre-filled syringe of NEPEXTO. Place the carton containing any remaining pre-filled syringe back into the refrigerator.

Please see section 5 for instructions on how to store NEPEXTO. If you have any questions about storage, contact your doctor, nurse, or pharmacist for further instructions.

2. Inspect the solution:

- Look at the medicine through the syringe body.
- The medicine should be clear or opalescent, colourless to yellow, and may contain small white or almost transparent particles of protein.
- Do not use the solution if it is discoloured, cloudy, or if particles other than those described above are present.

3. Allow the medicine to reach room temperature:

Remove one pre-filled syringe from the carton that is stored in the refrigerator and leave at room temperature for 15 to 30 minutes before injecting.

This is important to make the medicine easier and more comfortable to inject.

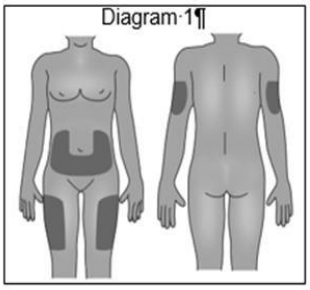
- Do not remove the needle cover until you are ready to inject.
- Do not use heat sources, such as a microwave or hot water, to warm the solution for injection.

4. Assemble the additional supplies you will need for your injection. These include an alcohol swab and a cotton ball or gauze.

5. Wash your hands with soap and warm water.

Step 2: Choosing an injection site

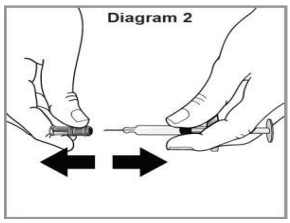
1. Three recommended injection sites include: (1) the front of the middle thighs; (2) the abdomen; and (3) the outer area of the upper arms (see Diagram 1). If you are injecting into the abdomen, choose a site that is at least 5 cm away from the belly button. If you are self-injecting, do not use the outer area of the upper arms.
2. A different site should be used for each new injection. Each new injection should be given at least 3 cm from an old site. Do not inject into areas where the skin is tender, bruised, red, or hard. Avoid areas with scars or stretch marks (it may be helpful to keep notes on the location of the previous injections).



3. If you have psoriasis, do not inject directly into any raised, thick, red, or scaly skin patches (“psoriasis skin lesions”).

Step 3: Injecting the solution

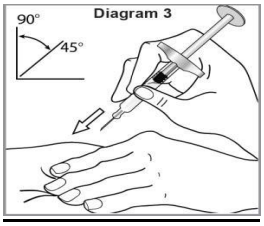
1. Wipe the skin at the injection site with an alcohol swab, using a circular motion. **Do NOT** touch this area again before giving the injection.
2. Pick up the pre-filled syringe from the flat work surface. Remove the needle cover by firmly pulling it straight off the syringe (see Diagram 2). **Do not twist or bend the needle cover while removing it, as this may damage the needle.**



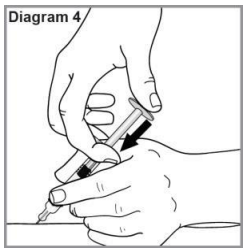
When you remove the needle cover, there may be a drop of liquid at the end of the needle; this is normal. Do not touch the needle or allow it to touch any surface. Do not touch or bump the plunger. Doing so could cause the liquid to leak out.

3. When the cleaned area of skin has dried, pinch and hold it firmly with one hand. With the other hand, hold the syringe like a pencil.

4. With a quick, short motion, push the needle all the way into the skin at an angle between 45° and 90° (see Diagram 3). With experience, you will find the angle that is most comfortable for you. Be careful not to push the needle into the skin too slowly, or with great force



5. When the needle is completely inserted into the skin, release the skin that you are holding. With your free hand, hold the syringe near its base to stabilise it. Then push the plunger to inject all of the solution at a slow, steady rate (see Diagram 4).



6. When the syringe is empty, pull the needle out of the skin, being careful to keep it at the same angle as inserted. There may be a little bleeding at the injection site. You can press a cotton ball or gauze over the injection site for 10 seconds. Do not rub the injection site. If needed, you may cover the injection site with a bandage.

Step 4: Disposing of supplies

See section 5.

Instructions for use for the pre-filled pen:

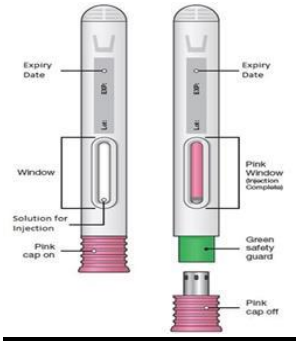
Read the Instructions for use before you start using NEPEXTO and each time you get a refill of your prescription. There may be new information.

- Do not try to give yourself the injection unless your doctor or nurse has shown you how to give the injection.

Not included in pack:

- Alcohol swab
- Gauze pad and plaster
- Sharps disposal container

Device Parts



A. Prepare for injection

Find a well-lit, clean flat surface and gather all the equipment you need.

1. Take the NEPEXTO carton containing the pre-filled pens out of the refrigerator and place it on a flat work surface. Remove one pre-filled pen and place it on your work surface. Do not shake the pre-filled pen. Place the carton containing any remaining pre-filled pen back into the refrigerator. Never recap the needle. Please see section 5 for instructions on how to store NEPEXTO. If you have any questions about storage, contact your doctor, nurse or pharmacist for further instructions.

• Do not use the pre-filled pen past the expiry date.

• Do not use the pre-filled pen if it has been dropped onto a hard surface (components inside the pre-filled pen may be broken).

• Do not use the pre-filled pen if the needle cap is missing or not securely attached.

2. Inspect the solution:

Look at the medicine through the viewing window.

• The medicine should be clear or opalescent, colourless or yellow, and may contain small white or almost transparent particles of protein.

• Do not use the solution if it is discoloured, cloudy, or if particles other than those described above are present.

3. Allow the medicine to reach room temperature:

Remove one pre-filled pen from the carton that is stored in the refrigerator and leave at room temperature for at least 30 minutes before injecting.

This is important to make the medicine easier and more comfortable to inject.

• Do not remove the needle cap until you are ready to inject.

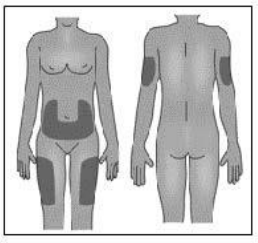
• Do not use heat sources, such as a microwave or hot water, to warm NEPEXTO.

4. Choose an injection site:

The pre-filled pen is for a subcutaneous injection.

It should be injected into the thigh, abdomen, or back of the upper arm (see image on the right).

Rotate the site for each injection.



If you are injecting into the abdomen, choose a site that is at least 5 cm away from the belly button.

• Do not inject into areas that are red, hard, bruised, or tender.

• Do not inject into scars or stretch marks.

• If you have psoriasis, do not inject into any raised, thick, red, or scaly skin patches, or lesions.

B. Injection steps Step 1:

Wash your hands with soap and water.

Step 2:

Wipe the skin at the injection site with an alcohol swab.

See ‘4. Choose an injection site’ for guidance with choosing an injection site.

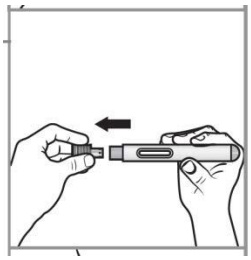
• Do not touch this area again before giving the injection.

Step 3:

Pull the needle cap straight off and dispose of it in the bin or sharps container.

• Do not twist or bend the needle cap while removing it, as this may damage the needle.

• Never recap the needle.



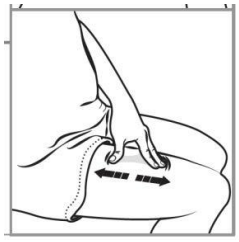
Step 4:

Gently stretch the skin at the cleaned injection site.

Position the pre-filled pen approximately 90 degrees to the skin.

• Do not pinch the skin.

• Stretching the skin creates a firm surface



Step 5:

Firmly press the pre-filled pen down into the site to start the injection.

The device will click when the injection begins.

Continue to hold the pre-filled pen firmly pressed into the site.

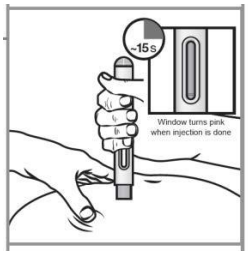
The device will click a second time.

Step 6:

After the second click, count slowly to 15 to make sure that the injection is complete.

• Do not release pressure against the injection site before the injection is complete.

• Do not move the pre-filled pen during the injection.



Step 7:

Remove the empty pen from the skin.

The needle guard will completely cover the needle.

Check for the pink plunger rod in the window to confirm that the full dose has been delivered.

Disposal:

See section 5.

C. Injection site care

If there is bleeding at the injection site, press a gauze pad over the injection site.

• Do not rub the injection site.

If needed, cover the injection site with a plaster.

If you use more NEPEXTO than you should

If you have used more NEPEXTO than you should (either by injecting too much on a single occasion or by using it too frequently), talk to a doctor or pharmacist immediately. Always have the outer carton of the medicine with you, even if it is empty.

If you forgot to inject a dose of NEPEXTO

If you forget a dose, you should inject it as soon as you remember, unless the next scheduled dose is the next day; in which case you should skip the missed dose. Then continue to inject the medicine on the usual day(s). If you do not remember until the day that the next injection is due, do not use a double dose (two doses on the same day) to make up for a forgotten dose.

4. Possible side effects

NEPEXTO can have side effects.

Not all side effects reported for NEPEXTO are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using NEPEXTO, please consult your health care provider for advice.

If any of the following happens, stop using NEPEXTO and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching,
- fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to NEPEXTO. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- Signs of serious infections, such as high fever that may be accompanied by cough, shortness of breath, chills, weakness, or a hot, red, tender, sore area on the skin or joints;

- Signs of blood disorders, such as bleeding, bruising, or paleness;
- Signs of nerve disorders, such as numbness or tingling, changes in vision, eye pain, or onset of weakness in an arm or leg;
- Signs of heart failure or worsening heart failure, such as fatigue or shortness of breath with activity, swelling in the ankles, a feeling of fullness in the neck or abdomen, night-time shortness of breath or coughing, bluish colour of the nails or the lips;
- Signs of cancers: Cancers may affect any part of the body including the skin and blood, and possible signs will depend on the type and location of the cancer. These signs may include weight loss, fever, swelling (with or without pain), persistent cough, presence of lumps or growths on the skin;
- Signs of autoimmune reactions (where antibodies are made that may harm normal tissues in the body) such as pain, itching, weakness, and abnormal breathing, thinking, sensation, or vision;
- Signs of lupus or lupus-like syndrome, such as weight changes, persistent rash, fever, joint or muscle pain, or fatigue;
- Signs of inflammation of the blood vessels such as pain, fever, redness or warmth of the skin, or itching.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent

- Infections (including colds, sinusitis, bronchitis, urinary tract infections and skin infections); injection site reactions (including bleeding, bruising, redness, itching, pain, and swelling) (these do not occur as often after the first month of treatment, some patients have developed a reaction at an injection site that was

recently used);

- headache.

Less frequent

- Serious infections (including pneumonia, deep skin infections, joint infections, blood infection, and infections at various sites);
- low red blood cell count, low white blood cell count, low neutrophil (a type of white blood cell) count;
- low blood platelet count;
- skin cancer (excluding melanoma);
- localised swelling of the skin (angioedema);
- hives (elevated patches of red or pale skin that often itch);
- eye inflammation;
- psoriasis (new or worsening);
- elevated liver blood tests (in patients also receiving methotrexate treatment, the frequency of elevated liver blood tests is common), abdominal cramps and pain, diarrhoea, weight loss or blood in the stool (signs of bowel problems);
- serious allergic reactions (including severe localised swelling of the skin and wheezing);
- lymphoma (a type of blood cancer);
- leukaemia (cancer affecting the blood and bone marrow); melanoma (a type of skin cancer);
- combined low platelet, red, and white blood cell count;
- nervous system disorders (with severe muscle weakness and signs and symptoms similar to those of multiple sclerosis or inflammation of the nerves of the eyes or spinal cord);

- tuberculosis;
- new onset congestive heart failure;
- seizures;
- skin rash, which may lead to severe blistering and peeling of the skin;
- lichenoid reactions (itchy reddish-purple skin rash and/or threadlike white-grey lines on mucous membranes);
- inflammation of the liver caused by the body's own immune system (autoimmune hepatitis; in patients also receiving methotrexate treatment, the frequency is uncommon);
- immune disorder that can affect the lungs, skin and lymph nodes (sarcoidosis);
- inflammation or scarring of the lungs (in patients also receiving methotrexate treatment, the frequency of inflammation or scarring of the lungs is uncommon);
- failure of the bone marrow to produce crucial blood cells.

Frequency unknown

- Merkel cell carcinoma (a type of skin cancer);
- Kaposi’s sarcoma (a type of cancer involving the lymph nodes or skin); excessive activation of white blood cells associated with inflammation (macrophage activation syndrome);
- recurrence of hepatitis B (a liver infection);
- worsening of a condition called dermatomyositis (muscle inflammation and weakness with an accompanying skin rash).

Side effects in children and adolescents

The side effects and their frequencies seen in children and adolescents are similar to those described above.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reactions & Quality Problem Reporting Form**", found online under SAHPRA's publications:

https://sahpra.org.za/wp-content/uploads/2020/01/6.04_ARF1_v5.1_27Jan2020.pdf

By reporting side effects, you can help provide more information on the safety of NEPEXTO.

5. How to store NEPEXTO

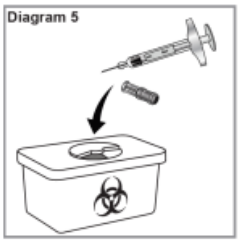
Store all medicines out of reach of children.

- Store in a refrigerator (2 °C – 8 °C).
- Do not freeze.
- Keep the pre-filled syringes or pens in the outer carton in order to protect from light.
- 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.
- Do not use after the expiry date stated on the label / carton.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

DISPOSAL OF THE PREFILLED SYRINGE

Step 4: Disposing of supplies

The pre-filled syringe is for single use only. The syringe and needle should NEVER be re-used. NEVER re-cap a needle. Dispose of the needle and syringe as instructed by your doctor, nurse or pharmacist (see Diagram 5).



DISPOSAL OF THE PREFILLED PEN

Disposal:

Dispose of the empty pen in an approved sharps container.
Check with your healthcare provider for instructions on how to properly dispose a filled sharps container.
Sharps disposal containers may be purchased at your local pharmacy.

- Do not throw the sharps container in household bin.
- Do not recycle.
- Always keep the container out of the sight and reach of children.

6. Contents of the pack and other information

NEPEXTO contains

- The active substance is etanercept.

  NEPEXTO 25 mg PS:

  Each pre-filled syringe contains 25 mg of etanercept.

  NEPEXTO 50 mg PS:

  Each pre-filled syringe contains 50 mg of etanercept.

  NEPEXTO 50 mg Prefill Pen:

  Each pre-filled pen contains 50 mg of etanercept.

  Etanercept is a human tumour necrosis factor receptor p75 Fc fusion protein produced by recombinant DNA technology in a Chinese hamster ovary (CHO) mammalian expression system. Etanercept is a dimer of a chimeric protein

genetically engineered by fusing the extracellular ligand binding domain of human tumour necrosis factor receptor 2 (TNFR2/p75) to the Fc domain of human IgG1. This Fc component contains the hinge, CH2 and CH3 regions, but not the CH1 region of IgG1. Etanercept contains 934 amino acids and has an apparent molecular weight of approximately 150 kilodaltons. The specific activity of etanercept is 1,7 × 106 units/mg.

- The other ingredients are sodium citrate, sodium dihydrogen phosphate dihydrate, glycine, sucrose, sodium chloride, water for injections.

What NEPEXTO looks like and contents of the pack

NEPEXTO solution is clear to opalescent, colourless to yellow and is formulated at pH 6,3 ± 0,2. The osmolality of the solution is 310 ± 30 mOsm/kg.

The solution is free of visible particulate matter.

NEPEXTO 25 mg PS

The syringe is made from a USP Type 1 clear glass Borosilicate Barrel with a 27 ½ inch G fixed injection needle and a rigid needle shield and stopper made by grey colour butyl rubber.

NEPEXTO is available in outer cardboard cartons packs containing 4 pre-filled syringes + 4 alcohol swabs, packs containing 12 pre-filled syringes + 12 alcohol swabs and multipack containing 24 pre-filled syringes and 24 swabs (2 packs of 12 pre-filled syringes + 12 alcohol swabs).

Not all pack sizes may be marketed.

NEPEXTO 50 mg PS

The syringe is made from a USP Type 1 clear glass Borosilicate Barrel with a 27 ½ inch G fixed injection needle and a rigid needle shield and stopper made by grey colour butyl rubber.

NEPEXTO is available in outer cardboard cartons packs containing 4 pre-filled syringes + 4 alcohol swabs and packs containing 12 pre-filled syringes + 12 alcohol swabs.

Not all pack sizes may be marketed.

NEPEXTO 50 mg Prefill Pen

Pre-filled pen containing a pre-filled syringe of NEPEXTO. The syringe is made from a USP Type 1 clear glass Borosilicate Barrel with a 27 ½ inch G fixed injection needle and a rigid needle shield and stopper made by grey colour butyl rubber.

NEPEXTO is available in outer cardboard cartons packs containing 4 pre-filled pens + 4 alcohol swabs and packs containing 12 pre-filled pens + 12 alcohol swabs.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

VIATRIS HEALTHCARE (PTY) LTD

4 Brewery street

Isando

Gauteng

Republic of South Africa

This leaflet was last revised in: 29 August 2023

Registration numbers

NEPEXTO 25 PS: 55/3.1/0521

NEPEXTO 50 PS: 55/3.1/0522

NEPEXTO 25 Prefilled Pen: 55/3.1/0523

Access to the corresponding Professional Information

To be confirmed.