

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using NEPEXTO?

NEPEXTO contains the active ingredient etanercept. NEPEXTO is used to treat specific types of joint inflammation and skin conditions, namely rheumatoid arthritis, juvenile idiopathic arthritis, ankylosing spondylitis, non-radiographic axial spondyloarthritis (nr-AxSpA), psoriatic arthritis and plaque psoriasis.

For more information, see Section [1. Why am I using NEPEXTO?](#) in the full CMI.

2. What should I know before I use NEPEXTO?

Do not use if you have ever had an allergic reaction to etanercept or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use NEPEXTO?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with NEPEXTO and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use NEPEXTO?

- NEPEXTO is given in adults either once a week as a 50 mg dose, or as two separate 25 mg doses 3-4 days apart.
- NEPEXTO should only be administered in children and adolescents weighing 62.5 kg or more. The dose and frequency depend on weight and the disease.
- NEPEXTO is injected under the skin and is for single use in one patient only. Refer to Instructions for Use provided in the pack.

More instructions can be found in Section [4. How do I use NEPEXTO?](#) in the full CMI.

5. What should I know while using NEPEXTO?

Things you should do	<ul style="list-style-type: none">• Remind any doctor or dentist you visit that you are using NEPEXTO.• Ensure children are up to date with vaccinations prior to starting NEPEXTO.• Tell your doctor if you are at risk of blood poisoning or infections, such as leg ulcers.• Contraception is recommended to avoid becoming pregnant during NEPEXTO therapy and for 3 weeks after discontinuation of NEPEXTO therapy. Inform your doctor immediately if you are planning pregnancy or are pregnant.
Things you should not do	<ul style="list-style-type: none">• Do not stop using this medicine suddenly, unless advised by your doctor• Do not shake the solution of NEPEXTO.
Looking after your medicine	<ul style="list-style-type: none">• Keep NEPEXTO in the fridge between 2°C and 8°C. Do not freeze.• Store NEPEXTO in the cartons to protect from light.

For more information, see Section [5. What should I know while using NEPEXTO?](#) in the full CMI.

6. Are there any side effects?

Common side effects include a mild reaction in the area of injection, infections and inflammation, allergic reactions, rash, itching, fever, headache and raised liver enzymes.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

NEPEXTO®

Active ingredient(s): *etanercept*

Consumer Medicine Information (CMI)

This leaflet provides important information about using NEPEXTO. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using NEPEXTO.**

Where to find information in this leaflet:

- [1. Why am I using NEPEXTO?](#)
- [2. What should I know before I use NEPEXTO?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use NEPEXTO?](#)
- [5. What should I know while using NEPEXTO?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using NEPEXTO?

NEPEXTO contains the active ingredient etanercept.

NEPEXTO is a biosimilar medicine to ENBREL. It has been assessed to be as safe and effective as the reference product and provides the same health outcomes.

Etanercept is a biotechnology-derived protein that works by binding to and inactivating Tumour Necrosis Factor (TNF), a naturally occurring chemical in your bloodstream that contributes to pain and swelling in the joints.

NEPEXTO is used in the treatment of specific inflammatory joint or skin conditions by reducing the pain and swelling of rheumatoid arthritis and psoriasis, helping to treat the skin lesions of psoriasis and psoriatic arthritis, and improving the condition of patients with ankylosing spondylitis, nonradiographic axial spondyloarthritis (nrAxSpA) and juvenile idiopathic arthritis.

Your doctor may have prescribed NEPEXTO for another reason. Ask your doctor if you have any questions about why NEPEXTO has been prescribed for you.

2. WHAT SHOULD I KNOW BEFORE I USE NEPEXTO?

Warnings

Do not use NEPEXTO if:

- you are allergic to etanercept, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.
- you have, or are at risk of developing, sepsis (blood poisoning), or long-term or localised infection (for example, leg ulcers)

Sepsis is a serious infection causing fever, headache, joint aches and pains, sore or weak muscles, and increased heart rate. NEPEXTO can affect your body's ability to fight a serious infection.

If you are not sure whether you have a serious infection, check with your doctor.

- you are currently taking anakinra or other similar medicines known as Interleukin-1 antagonists.
- the packaging is torn or shows signs of tampering
- the expiry date printed on the pack has passed.

If you use NEPEXTO after the expiry date has passed, it may have no effect at all, or worse, have an entirely unexpected effect.

Check with your doctor if you:

- have any allergies to:
 - any other medicines,
 - any other substances, such as foods, preservatives or dyes.
- have any other medical conditions, especially:
 - serious infection including sepsis, tuberculosis or a history of recurring infections,
 - low resistance to disease,
 - diabetes,
 - liver problems or hepatitis B or hepatitis C, viruses that affect the liver,
 - heart failure,
 - blood disorders,
 - cancer,
 - are about to have major surgery,
 - nerve disorders including multiple sclerosis or
 - optic neuritis (inflammation of the nerves of the eyes),
 - seizures,
 - chickenpox or have been recently exposed to chickenpox.
- take any medicines for any other condition,
- you are pregnant or intend to become pregnant,
- you are breast-feeding or plan to breast-feed.

If you are not sure whether you should start taking this medicine, talk to your doctor.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

The effects of NEPEXTO in pregnant women are not well understood, therefore NEPEXTO should only be used during pregnancy if clearly needed.

Contraception is recommended to avoid becoming pregnant during NEPEXTO therapy and for 3 weeks after discontinuation of NEPEXTO therapy. Inform your doctor immediately if you are planning pregnancy or are pregnant.

If you become pregnant while using NEPEXTO, contact your doctor. Your doctor will help you to decide whether the benefits of treatment outweigh the potential risk to your baby.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

Small amounts of NEPEXTO can pass into breast milk. If you are breastfeeding, you should discuss the use of NEPEXTO and the options available with your doctor.

It is important that you discuss with your doctor the use of NEPEXTO during pregnancy or breastfeeding before the baby receives any vaccine.

Use in children

- NEPEXTO is not currently recommended for use in children under 2 years of age as it has not been tested in children under 2 years.
- Make sure that children are up to date with all vaccinations (including chickenpox) before they start treatment with NEPEXTO.
- Live vaccines, such as oral polio vaccine, should not be given while receiving NEPEXTO.

This medicine is available only with a doctor's prescription. NEPEXTO is not addictive.

3. What if I am taking other medicines?

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

Some medicines may interfere with NEPEXTO and affect how it works.

Medicines that increase risk of side effect when used with NEPEXTO:

- abatacept and Interleukin-1 antagonists such as anakinra. These medicines should not be used with NEPEXTO.
- cyclophosphamide, a medicine used to treat cancer or prevent transplant rejection. Use with NEPEXTO is not recommended.
- sulfasalazine.

Medicines that NEPEXTO may interfere with:

- some vaccines
- warfarin, a medicine used to thin the blood and prevent blood clots
- digoxin, a medicine used to improve the strength and efficiency of the heart, or to control the rate and rhythm of the heartbeat
- medicines used to treat diabetes

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect NEPEXTO.

4. How do I use NEPEXTO?

Your doctor will tell you how to inject NEPEXTO. A different site should be used for each new injection. Each new injection should be given at least 3 cm from an old site.

How much to use

Adults

- The recommended dose for adults is 50 mg per week, injected under the skin. This can be given as either a single 50 mg injection once weekly, or two separate 25 mg injections, 3-4 days apart. Your doctor may determine a different frequency at which to inject NEPEXTO.
- If you are being treated for psoriasis, your doctor may prescribe a higher dose of NEPEXTO when you first begin your treatment.
- If you are being treated for nr-AxSpA and NEPEXTO has no effect on your condition within 12 weeks, your doctor may tell you to stop using this medicine.
- Follow the instructions provided and use NEPEXTO until your doctor tells you to stop.

Children

- NEPEXTO should only be administered in children and adolescents weighing 62.5 kg or more.
- The appropriate dose and frequency of dosing for children and teenagers will depend on body weight and the disease. Your child's doctor will provide detailed directions for preparing and measuring the appropriate dose for your child.
- For juvenile idiopathic arthritis, the recommended dose is 0.8 mg of NEPEXTO per kg bodyweight (up to a maximum of 50 mg) given once weekly. NEPEXTO may also be given twice weekly at a dose of 0.4 mg of NEPEXTO per kg bodyweight (up to a maximum of 25 mg).
- For psoriasis patients, the recommended dose is 0.8 mg of NEPEXTO per kg bodyweight (up to a maximum of 50 mg) 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.

When to use NEPEXTO

This section is divided into the following subsections:

A: Setting up for an injection

B: Choosing an injection site

C: Injecting the NEPEXTO solution

D: Disposing of supplies

Introduction

The following instructions explain how to prepare and inject NEPEXTO. Please read the instructions carefully and follow them step by step. Please read the instructions each

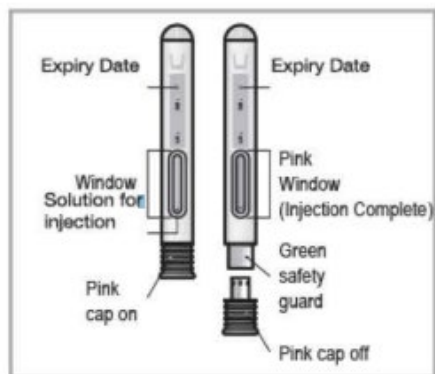
time you get a refill of your prescription. There may be new information.

You will be instructed by your doctor or his/her assistant on the techniques of self-injection. Do not attempt to administer an injection until you are sure that you understand how to prepare and give the injection.

This pack contains 1 or 4 x pre-filled auto-injectors containing 50 mg of NEPEXTO solution. This pack does not contain gauze pads, alcohol swabs and adhesive strips or Sharps disposal containers.

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

Device Parts



A: Setting up for an injection

1. Select a clean, well-lit, flat working surface.
2. Take the NEPEXTO carton containing the autoinjectors out of the refrigerator and place it on a flat work surface together with a cotton ball or gauze pad and adhesive strip. Remove one auto-injector and one alcohol swab and place them on your work surface.

Do not shake the auto-injector of NEPEXTO. Place the carton containing any remaining auto-injectors back into the refrigerator.

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

3. Allow the solution to reach room temperature.

- You should allow at least 30 minutes for the NEPEXTO solution to reach room temperature 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 warm NEPEXTO in any other way (for example, do not warm it in a microwave or in hot water).

4. Inspect the auto-injector.

- Check the expiry date on the auto-injector label.
- Do not use the auto-injector past the expiration date.

- Do not use the auto-injector if it has been dropped onto a hard surface - components inside the auto-injector may be broken.
- Do not use the auto-injector if the needle cap is missing or not securely attached.

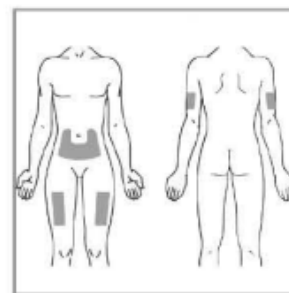
5. Inspect the solution in the auto-injector.

- Look at the medicine through the viewing window. It should be clear or slightly opalescent, colourless or pale yellow, and may contain small white or almost transparent particles of protein. This appearance is normal for NEPEXTO.
- Do not use the solution if it is discoloured, cloudy, or if particles other than those described are present.
- If you are concerned with the appearance of the solution, then contact your pharmacist for assistance.

B: Choosing an injection site

1. NEPEXTO solution is for a subcutaneous injection. The recommended injection sites for NEPEXTO using an auto-injector include:

- (1) the middle of the front of your thighs;
- (2) the abdomen, choosing a site that is at least 5 cm away from your belly button; and
- (3) the outer area of your upper arms.



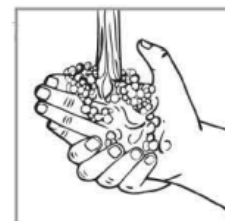
If you are self-injecting, you should NOT USE the outer area of the upper arms

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, you should try not to inject directly into any raised, thick, red, or scaly skin patches ("psoriasis skin lesions").

C: Injecting the NEPEXTO solution

Step 1:

- Refer to the instructions in Section A of this leaflet to set up for your injection.
- Wash your hands with soap and water.



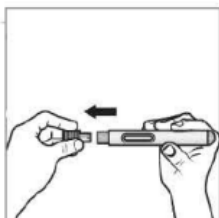
Step 2:

- 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.
- See "Choosing an injection site" for guidance with choosing an injection site.



Step 3:

- Remove the needle cap by firmly pulling it straight off the auto-injector.
- 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.

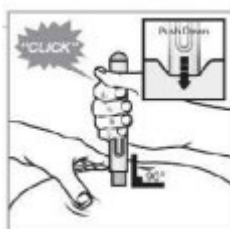
Step 4:

- When the cleaned area of skin has dried, gently stretch the skin at the cleaned injection site with one hand. With the other hand, position the auto-injector approximately 90° to the skin.
- Do not pinch the skin. Stretching the skin creates a firm surface.



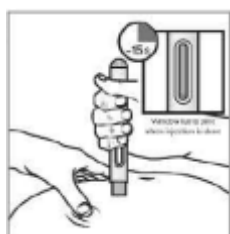
Step 5:

- Firmly press the auto-injector down into the site to start the injection. The auto-injector will click when the injection begins.
- Continue to hold the autoinjector firmly pressed into the site. The auto-injector 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 auto-injector during the injection.



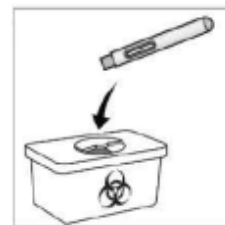
Step 7:

- Remove the empty autoinjector 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.



Step 8:

- The auto-injector is for single-use administration only.
- The auto-injector should NEVER be re-used. NEVER recap a needle.



Dispose of the auto-injector in a Sharps container or as instructed by your doctor, nurse or pharmacist.

Check with your healthcare provider for instructions on how to properly dispose of a filled Sharps container. Sharps disposal containers may be purchased at your local pharmacy. Do not throw the Sharps container in the household bin. Do not recycle. Always keep the container out of the sight and reach of children.

D: Injection site care

- 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.

If needed, cover the injection site with a bandage. Do not rub the injection site.

If you have any questions or require further information, please talk with your doctor, nurse or pharmacist.

If you forget to use NEPEXTO

NEPEXTO should be used regularly at the same time each week, or the same time every 3-4 days as agreed with your doctor. If you miss your dose at the usual time, you should inject the next dose as soon as you remember if it is within 48 hours since the scheduled dose time.

If it is almost time for your next dose i.e. within 48 hours of your next dose, skip the dose you missed and take your next dose when you are meant to.

Do not take a double dose to make up for the dose you missed.

If you use too much NEPEXTO

If you think that you have used too much NEPEXTO, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26) for advice, or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

Always take the labelled medicine carton with you, even if it is empty.

You may need urgent medical attention. There is very limited data on overdose with NEPEXTO. Ask your doctor if you have any concerns.

5. What should I know while using NEPEXTO?

Things you should do

Tell any other doctors, dentists and pharmacists who are treating you that you are using NEPEXTO.

Tell your doctor if NEPEXTO is not making your condition better.

Call your doctor straight away if you:

- Have or develop any serious infection while using NEPEXTO. Do not inject any more NEPEXTO and contact your doctor immediately.
- Have any symptoms such as persistent fever, sore throat, bruising, bleeding or paleness.

These symptoms may point to the existence of a potentially life-threatening blood disorder, which may require you to stop taking NEPEXTO.

Remind any doctor, dentist or pharmacist you visit that you are using NEPEXTO.

Things you should not do

- Do not stop using this medicine suddenly or lower the dosage without checking with your doctor.
- Do not shake the solution of NEPEXTO. Shaking the solution will cause it to froth (create lots of bubbles). This may affect the medicine so that it may not work.
- Do not stop using NEPEXTO because you are feeling better, unless your doctor advises you to. Your condition may flare up if you reduce the dose or stop using NEPEXTO.
- Do not give NEPEXTO to anyone else even if they have the same condition as you.
- Do not use NEPEXTO to treat any other complaints unless your doctor tells you to.
- Do not stop using NEPEXTO, or lower the dosage, without checking with your doctor.

Driving or using machines

It is not known whether NEPEXTO causes dizziness or drowsiness.

Drinking alcohol

No information is available.

Looking after your medicine

Follow the instructions in the carton on how to take care of your medicine properly.

Keep NEPEXTO in a refrigerator where the temperature stays between 2°C and 8°C.

Keep it away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Store NEPEXTO and auto-injectors in their cartons to protect them from light.

Heat and dampness can destroy some medicines.

If it is not possible to store NEPEXTO in the refrigerator, it may be stored out of the refrigerator (below 25°C) for up to 4 weeks (e.g. when travelling).

If you have stored NEPEXTO at room temperature for any period of time (even if returned to the refrigerator) you must use it within 4 weeks from the time you first took it out of the refrigerator, or else you must discard it.

Do not use NEPEXTO if it has been exposed to temperatures above 25°C or has been out of the refrigerator for more than 4 weeks.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Common side effects

Common side effects	What to do
Injection site reactions: <ul style="list-style-type: none">• Itching• Bruising• Redness• Bleeding, swelling, pain or hardness around the injection site. Infections: <ul style="list-style-type: none">• Cold• Sinus infections Allergic reactions: <p>Symptoms of an allergic reaction may include:</p> <ul style="list-style-type: none">• wheezing, shortness of breath, difficulty breathing, or a tight feeling in your chest,• swelling of the face, lips, tongue or other parts of the body,• rash, itching, hives or flushed red skin,• dizziness or light-headedness. Other: <ul style="list-style-type: none">• Headaches• Fever	Speak to your doctor if you have any of these common side effects and they worry you.

Serious side effects

Serious side effects	What to do
<p>Infections:</p> <ul style="list-style-type: none"> Tuberculosis Blood poisoning (sepsis) Signs of an infection such as fever, chills, mouth ulcers or sore throat <p>Lung disease:</p> <ul style="list-style-type: none"> Breathlessness during exercise or a dry cough <p>Soft tissue infections:</p> <ul style="list-style-type: none"> Bumps or sores that do not heal, are swollen, red or have pus <p>Nervous system disorders:</p> <ul style="list-style-type: none"> Seizures, numbness or tingling throughout your body, weakness in your arms and/or legs and dizziness, or problems with your eyesight. <p>Inflammation:</p> <ul style="list-style-type: none"> Spinal cord Inner eye Blood vessels in the skin or lymph glands Signs of inflammatory bowel such as diarrhoea or mucus or blood in your stools, stomach cramps, fever or weight loss. Signs your kidneys may not be functioning properly, including urinating less often, pink/dark brown, foamy/bubbly urine, swelling of the face, hands, feet and abdomen, and high blood pressure. <p>Allergic reaction:</p> <ul style="list-style-type: none"> Swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing, or hives. <p>Lupus or lupus-like syndrome:</p> <ul style="list-style-type: none"> Weight changes, persistent rash, fever, joint or muscle pain or fatigue <p>Immune system disorders:</p> <ul style="list-style-type: none"> Skin rash, blisters and ulcers on the skin, in the mouth or airways <p>Blood disorders:</p> <ul style="list-style-type: none"> Tiredness, headaches, shortness of breath when exercising, dizziness, paleness, nose bleeds, 	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

Serious side effects	What to do
<p>unusual bleeding or bruising or more frequent infections.</p> <p>Heart failure:</p> <ul style="list-style-type: none"> shortness of breath, persistent cough, difficulty exercising, fast or irregular heartbeat, swelling in the legs or feet, tiredness and weakness 	

There have been reports of some types of cancer developing in patients using NEPEXTO and other TNF blocking medicines. These include skin cancers, cancers that affect the lymph system called lymphoma and Kaposi's sarcoma (which also affects the organs, skin, mouth, nose or throat), or affect the blood system called leukaemia. The role of NEPEXTO in the development of cancer is not known.

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What NEPEXTO contains

Active ingredient (main ingredient)	Etanercept
Other ingredients (inactive ingredients)	<p>Sodium citrate dihydrate</p> <p>Monobasic sodium phosphate dihydrate</p> <p>Glycine</p> <p>Sucrose</p> <p>Sodium chloride</p> <p>Water for Injections</p>

Do not take this medicine if you are allergic to any of these ingredients.

What NEPEXTO looks like

The NEPEXTO auto-injector is supplied in packs containing 1 or 4 single-dose pre-filled auto-injectors containing NEPEXTO solution.

Each auto-injector contains 50 mg of etanercept in 1 mL of NEPEXTO solution.

The auto-injector consists of a syringe made from clear Type 1 glass with a stainless steel 27 gauge needle, needle cover cap and plastic plunger. The needle cap of the prefilled auto-injector does not contain dry natural rubber (a derivative of latex) (AUST R 386938).

Who sponsors NEPEXTO

Maxx Pharma Pty Ltd

Level 20, 181 William St,

Melbourne Victoria 3000

Phone: 1800 202 981

Email: medical@maxxpharma.com.au

Who distributes NEPEXTO

Generic Health Pty Ltd

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Phone: 03 9809 7900

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