

# Neoral®

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## 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 Neoral?

Neoral contains the active ingredient ciclosporin. Neoral is used to prevent organ rejection in people who have had kidney, liver or heart transplant. It is also used to treat different diseases that occur due to issues with your immune system such as nephrotic syndrome (a kidney disease), severe active rheumatoid arthritis (a joint disease having pain, swelling and stiffness in joints), severe psoriasis (a skin disease that causes rash with itchy scaly patches), severe atopic dermatitis (a skin disease that causes dry itchy and inflamed skin).

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

### 2. What should I know before I use Neoral?

Do not use if you have ever had an allergic reaction to Neoral 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 Neoral?](#) in the full CMI.

### **3. What if I am taking other medicines?**

Some medicines may interfere with Neoral 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 Neoral?**

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

### **5. What should I know while using Neoral?**

<b>Things you should do</b>	<ul style="list-style-type: none"><li>● Remind any doctor, dentist or pharmacist you visit that you are using Neoral.</li><li>● If you develop any lumps anywhere on/in your body, or develop any moles, or you notice changes in existing</li></ul>
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	<p>moles, tell your doctor immediately.</p> <ul style="list-style-type: none"> <li>● Limit your exposure to sunlight and UV light.</li> <li>● Avoid taking this medicine with grapefruit, grapefruit juice or a fatty meal.</li> <li>● Avoid eating large amounts of foods that are high in potassium content.</li> <li>● Take special care of your teeth and gums and see your dentist regularly.</li> </ul>
<p><b>Things you should not do</b></p>	<ul style="list-style-type: none"> <li>● Do not have any vaccinations without first consulting with your doctor.</li> <li>● Do not stop treatment unless your doctor tells you to.</li> </ul>
<p><b>Driving or using machines</b></p>	<ul style="list-style-type: none"> <li>● Neoral may make you feel sleepy, dizzy, have blurred vision or headaches. Take care driving until you know how it affects you.</li> </ul>

<b>Drinking alcohol</b>	<ul style="list-style-type: none"> <li>• Your doctor may ask you to limit your alcohol intake.</li> </ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"> <li>• Neoral 10mg capsules are stored below 25°C and the 25mg, 50mg &amp; 100mg capsules are stored below 30°C. Neoral oral solution is stored between 15-30°C.</li> </ul>

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

## 6. Are there any side effects?

Neoral may increase your risk of infections, cause headache, tiredness, tremors, burning sensation in the hands or feet, excess hair growth, vomiting, feeling sick, swollen or puffy gums, allergic reactions such as hives, rash, itchy skin.

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.

# Neoral®

**Active ingredient(s):** *ciclosporin*

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## Consumer Medicine Information (CMI)

This leaflet provides important information about using Neoral. **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 Neoral.**

**Where to find information in this leaflet:**

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

## 1. Why am I using Neoral?

**Neoral contains the active ingredient ciclosporin.** Neoral belongs to group of medicines known as immunosuppressive agents. These medicines help to control your body's immune system.

**Neoral is used for people who have had a kidney, liver or heart transplant, to prevent the body from rejecting a new organ.** It does this by blocking the development of special cells which would normally attack the transplanted tissue.

**It is also used to treat other conditions which are thought to be caused by a problem with your immune system:**

- Nephrotic syndrome (a kidney disease)
- Severe active rheumatoid arthritis (a disease affecting the joints with pain and swelling)
- Severe psoriasis (a skin disease with thickened patches of red skin, often with silvery scales)
- Severe atopic dermatitis (a skin allergy causing dry itchy and inflamed skin).

## **2. What should I know before I use Neoral?**

### **Warnings**

**Do not use Neoral if:**

- you are allergic to ciclosporin or any of the ingredients listed at the end of this leaflet.

Symptoms of allergic reactions may include flushing of face or area between neck and tummy area, shortness of breath or difficulty in breathing, coughing up blood, shortness of breath, wheezing, blood pressure changes and fast heartbeat.

Your doctor may discontinue if you develop allergic reactions.

Always check the ingredients to make sure you can use this medicine.

**Do not use Neoral if you are taking it for non-transplant related conditions and you have:**

- uncontrolled high blood pressure
- any uncontrolled infection.

**Use in children**

Do not give Neoral to patients under 16 years of age to treat severe rheumatoid arthritis, psoriasis or atopic dermatitis. However, it can be used in children younger than 16 years of age who have had an organ transplant or who have a kidney disease (nephrotic syndrome).

**Check with your doctor if you have:**

- Kidney problems - Neoral should not be taken by some patients with impaired kidney function.
- Any type of cancer or conditions that may develop into cancer.
- Vaccinations planned as these may be less effective during treatment with Neoral. Use of live attenuated vaccines should be avoided.
- Liver problems
- Severe heart, lung or blood vessel disease.

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.**

There is an increased risk of problems in the mother and unborn child with the use of Neoral or any immunosuppressive therapy in general.

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

Breast-feeding is not recommended if you are on treatment with Neoral. Ciclosporin, the main ingredient of the medicine, passes into the breast milk and can cause serious problems for the baby.

## **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 Neoral and affect how it works. Let your doctor know if you are using any of the following drugs:**

- Methotrexate, a medicine used to treat rheumatoid arthritis

- Antibiotics, medicines used to treat infections, e.g. erythromycin, clarithromycin, azithromycin, rifampicin, ciprofloxacin, trimethoprim, gentamicin, tobramycin, vancomycin
- Antibacterial medicines used to treat tuberculosis e.g. nafcillin, rifampicin
- Antifungal medicines, e.g. fluconazole, ketoconazole, itraconazole, voriconazole, amphotericin B, terbinafine
- Tacrolimus, everolimus, sirolimus, mycophenolate sodium, other medicines which are used to suppress the immune system
- Diuretics (water tablets), a medicine that increases your amount of urine passed
- Heart or blood pressure medicines, e.g. lercanidipine, nifedipine, amlodipine, verapamil, diltiazem, nicardipine, bosentan
- Digoxin, a medicine used to treat heart failure
- Statins, medicines used to treat high cholesterol, e.g. simvastatin, atorvastatin, pravastatin
- Fenofibrate, a medicine used to treat high cholesterol
- Probucol, an agent used to lower cholesterol
- Certain medicines used to prevent fits or seizures e.g. carbamazepine, phenytoin
- Corticosteroid e.g. high doses of Methylprednisolone, a medicine used to treat inflammatory diseases such as arthritis, asthma, colitis
- Medicines used to treat gout e.g. colchicine, sulfinpyrazone, allopurinol
- NSAIDs (non-steroid anti-inflammatory drugs), used to treat pain e.g. diclofenac, naproxen, indomethacin

- Recombinant human erythropoietin (rhEPO), a medicine used to treat specific types of anaemia
- Repaglinide, a medicine used to treat diabetes
- Cannabidiol (medicinal cannabis)
- Certain medicines used to decrease the amount of acid in your stomach, e.g. cimetidine, ranitidine.
- Some oral contraceptives medicines, e.g. levonorgestrel and norethisterone
- Protease inhibitors used to treat HIV
- Etoposide, imatinib, doxorubicin, medicines used to treat certain cancers
- Octreotide, a medicine used to treat a condition called acromegaly, and certain types of cancer
- Cholic acid and derivatives, medicines used to treat gallstones
- Metoclopramide, a medicine used to treat nausea and vomiting
- Orlistat, a medicine used to help with weight loss
- St John's wort, a herbal supplement used to treat conditions such as depression.
- Nefazodone, a medicine used to treat depression.

**Consult your doctor or pharmacist if you are taking any other medicines.**

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

## 4. How do I use Neoral?

### How much to take

Neoral is available as capsules and as an oral solution.

- Your doctor will determine the correct dose for you. It will depend on how much you weigh, what condition you are taking it for, how well Neoral works for you, and whether you have any side effects from this medicine.
- Your doctor may adjust your dose based on your response to the medicine.
- Follow the instructions provided. Check with your doctor or pharmacist if you are not sure how much to take.

### When to take Neoral

- Take Neoral in the morning and at night.

### How to take Neoral:

#### Capsules

- Do not remove the capsules from the foil blister pack until you are ready to take them.
- Swallow the capsules whole with a full glass of water.
- Do not chew them.

## Oral solution

The oral solution is provided with two syringes for measuring the doses. The 1-mL syringe is used to measure doses less than or equal to 1 mL (each graduation of 0.05 mL corresponds to 5 mg of cyclosporin). The 4-mL syringe is used to measure doses greater than 1 mL and up to 4 mL (each graduation of 0.1 mL corresponds to 10 mg of cyclosporin). The oral solution should be diluted in a glass, not plastic container.

- Measure out the dose using the syringe provided.
- Add the dose to a glass of orange juice, apple juice or soft drink just before you take it. Do not use grapefruit juice.
- Make sure the syringe does not touch the liquid in the glass.
- Stir the liquid well immediately before drinking it.
- Rinse the container with more juice or soft drink to make sure that the whole dose has been taken.
- Wipe the outside of the syringe with a clean, dry tissue and put it back into its case. Do not wash the syringe with water, alcohol or any other liquid.

## 5. What should I know while using Neoral?

### Things you should do

**Keep all your medical appointments.**

Your doctor will do routine tests to monitor your blood levels, to check how well your kidneys and liver are working, and to decide if your dose needs to be changed.

**Limit your exposure to sunlight and UV light.**

If you go out in the sun, wear a hat, appropriate protective clothing and use sunscreen with a high protection factor.

This will help prevent the risk of developing skin cancer.

**Avoid eating large amounts of foods that are high in potassium content.**

Taking Neoral can increase the amount of potassium in your blood. Too much potassium will cause unwanted side effects. Check with your doctor or pharmacist if you are not sure what foods contain high amounts of potassium.

**Avoid taking this medicine with grapefruit, grapefruit juice or a fatty meal as it may cause unwanted side effects.**

**Take special care of your teeth and gums and see your dentist regularly.**

Neoral may increase your risk of gum disease.

**Call your doctor straight away if you:**

- develop any lumps anywhere on/in your body, or develop any moles, or you notice changes in existing moles.
- become pregnant while having Neoral

- experience any symptoms of infection (e.g. fever, sore throat).

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

## **Things you should not do**

- Do not stop treatment unless your doctor or healthcare professional tells you.
- Do not have any vaccinations without first consulting with your doctor.

## **Driving or using machines**

**Be careful before you drive or use any machines or tools until you know how Neoral affects you.**

Neoral may make you feel sleepy, dizzy, have blurred vision or headaches.

If your child is on Neoral, check how the medicine affects them before they ride a bike or do activities that need coordination and concentration.

## **Drinking alcohol**

**Tell your doctor if you drink alcohol.**

Drinking alcohol while on treatment with Neoral may lead to unwanted effects. Your doctor may ask you to limit your alcohol intake.

## Looking after your medicine

### Capsules

10 mg capsules: Store below 25°C.

25 mg, 50 mg, 100 mg capsules: Store below 30°C.

### Oral solution

Store between 15-30°C. Do not refrigerate. Throw away 2 months after opening the bottle.

Store the capsules and oral solution in a cool dry place 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 windowsills.

**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.

## Less serious side effects

Less serious side effects	What to do
<p><b>General problems:</b></p> <ul style="list-style-type: none"> <li>• Fever</li> <li>• Swelling in the hands or feet</li> <li>• Feeling more tired than normal</li> <li>• Headache</li> <li>• Dizziness</li> <li>• Confusion</li> <li>• Feeling of tingling, numbness</li> <li>• Burning sensation in hands and feet (usually during the first week of treatment)</li> <li>• Tremor, shakiness</li> </ul> <p><b>Gastrointestinal problems:</b></p> <ul style="list-style-type: none"> <li>• Loss of appetite</li> <li>• Swelling of the gums</li> <li>• Feeling sick, vomiting</li> </ul>	<p><b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b></p>

<b>Less serious side effects</b>	<b>What to do</b>
<ul style="list-style-type: none"> <li>● Diarrhoea</li> <li>● Pain or discomfort in the tummy</li> </ul> <p><b>Skin problems:</b></p> <ul style="list-style-type: none"> <li>● Excessive growth of body and facial hair, particularly in women</li> <li>● Acne</li> <li>● Skin rash</li> <li>● Flushing of the face</li> </ul> <p><b>Reproductive system issues:</b></p> <ul style="list-style-type: none"> <li>● Painful or no menstrual periods</li> <li>● Increased breast size in males</li> </ul> <p><b>Muscle problems:</b></p> <ul style="list-style-type: none"> <li>● Muscle cramps</li> <li>● Pain or tenderness in the muscles</li> </ul>	

## Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"><li>● Sudden swelling of the face, lips, tongue, or throat; difficulty breathing; rash or hives; feeling faint or dizzy</li><li>● High fever, chills, feeling very unwell, confusion, rapid heartbeat, trouble breathing</li><li>● Unusual bruising or bleeding, frequent infections (fever, chills, sore throat), extreme tiredness or weakness</li><li>● Severe headache, sudden confusion, trouble seeing, hallucinations, difficulty speaking, seizures</li><li>● Severe stomach pain, swelling of the tummy area, vomiting blood, black or bloody stools, yellowing of the skin or eyes</li><li>● Yellowing of the skin or eyes, dark urine, severe</li></ul>	<p><b>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.</b></p>

<b>Serious side effects</b>	<b>What to do</b>
<p>tiredness, pain in the upper right side of the tummy area</p> <ul style="list-style-type: none"> <li>● Muscle cramps, weakness, confusion, irregular heartbeat, fainting, seizures</li> <li>● Aching muscles, muscle tenderness or weakness, not caused by exercise</li> <li>● Little or no urine, bloody or smelly urine</li> <li>● New lumps or moles, or changes to existing moles</li> </ul>	

**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.

Some side effects may not give you any symptoms and can only be found when tests are done.

## **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](http://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 Neoral contains

<b>Active ingredient (main ingredient)</b>	ciclosporin
<b>Other ingredients (inactive ingredients)</b>	Capsules and Oral solution: <ul style="list-style-type: none"><li>• dl--tocopherol</li><li>• propylene glycol</li><li>• corn glycerides</li><li>• polyoxyl 40 hydrogenated castor oil</li><li>• Alcohol (as ethanol 11.8% v/v in the capsules and ethanol 12% v/v in the oral solution)</li></ul>

	<p>Capsules also contain:</p> <ul style="list-style-type: none"> <li>● gelatin</li> <li>● glycerol</li> <li>● titanium dioxide</li> <li>● iron oxide black CI 77499 (25 and 100 mg capsules only)</li> <li>● carminic acid CI 75470 (printing ink)</li> <li>● aluminium chloride (printing ink)</li> <li>● sodium hydroxide (printing ink)</li> <li>● hydroxypropyl methylcellulose 2910 (printing ink).</li> </ul>
<b>Potential allergens</b>	Contains ethanol

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

### **What Neoral looks like**

Neoral 10mg capsules: yellow-white, oval soft gelatin capsules printed in red ink with "NVR" and "10".  
Supplied in foil blister packs of 60 capsules.

Neoral 25mg capsules: blue-grey, oval soft gelatin capsules imprinted in red ink with "NVR" and "25".  
Supplied i in foil blister packs of 30 capsules.

Neoral 50mg capsules: yellow-white, oval soft gelatin capsules imprinted in red ink with "NVR" and "50".  
Supplied in foil blister packs of 30 capsules.

Neoral 100mg capsules: blue-grey, oval soft gelatin capsules imprinted in red ink with "NVR" and "100".  
Supplied in foil blister packs of 30 capsules.

Neoral 100mg/ml oral solution: Clear, faintly yellow-brownish liquid in a 50 mL glass bottle, with a 1mL and 4mL syringe for measuring the dose.

Australian Registration Numbers:

Neoral 10mg capsule AUST R 59614

Neoral 25mg capsule AUST R 49722

Neoral 50mg capsule AUST R 49723

Neoral 100mg capsule AUST R 49724

Neoral 100mg/ml oral solution AUST R 49725

## **Who distributes Neoral**

Neoral is supplied in Australia by:

NOVARTIS Pharmaceuticals Australia Pty Limited

ABN 18 004 244 160

54 Waterloo Road

Macquarie Park NSW 2113

Telephone: 1 800 671 203

Website: [www.novartis.com.au](http://www.novartis.com.au)

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