

Neoral®

cyclosporin

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Neoral.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

The information in this leaflet was last updated on the date listed on the final page. More recent information on the medicine may be available.

You should ensure that you speak to your pharmacist or doctor to obtain the most up to date information on the medicine. You can also download the most up to date leaflet from www.novartis.com.au.

Those updates may contain important information about the medicine and its use of which you should be aware.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking Neoral against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What Neoral is used for

Neoral is used for people who have had a kidney, heart or liver transplant, to prevent the body from rejecting the new organ. It does this by blocking the development of

special cells which would normally attack the transplanted tissue.

Neoral is also used to treat several other conditions which are thought to be caused by a problem with the immune system:

- a kidney disease called nephrotic syndrome
- severe cases of rheumatoid arthritis (a disease, affecting the joints with pain and swelling)
- severe cases of:
 - psoriasis (a skin disease with thickened patches of red skin, often with silvery scales)
 - atopic dermatitis (skin allergies)

Neoral contains the active ingredient, cyclosporin. It belongs to a group of medicines called immuno-suppressive agents. These medicines help to control your body's immune system.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

Neoral is only available with a doctor's prescription. It is not addictive.

Before you take Neoral

When you must not take it

Do not take Neoral if you have ever had an allergic reaction to cyclosporin, the active ingredient in Neoral, or to any of the other ingredients listed at the end of this leaflet.

Symptoms of an allergic reaction may include hives or an itchy skin rash, swelling of the face, lips or tongue, faintness, wheezing or troubled breathing.

If you think you may be allergic to Neoral, ask your doctor for advice.

Do not take Neoral after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

In that case, return it to your pharmacist.

Do not give Neoral to a child under 16 years of age to treat severe rheumatoid arthritis, psoriasis or atopic dermatitis.

There is not enough information to recommend its use for these diseases in children under 16 years of age. However, Neoral can be used in children younger than 16 who have had an organ transplant or who have nephrotic syndrome.

Before you start to take it

If you have been prescribed Neoral for nephrotic syndrome, rheumatoid arthritis, psoriasis or atopic dermatitis, tell your doctor if you also have any of these health problems/medical conditions:

- high blood pressure that is not controlled
- any uncontrolled infection

- a poorly functioning immune system
- problems with your kidneys or liver
- severe heart, lung or blood vessel disease
- any type of cancer, including skin cancer

Your doctor may not want you to take Neoral or may want to take special precautions if you have any of these conditions.

If you are being treated with Neoral for psoriasis or atopic dermatitis, you should not concurrently receive UVB-rays or phototherapy.

Tell your doctor if you are pregnant or intend to become pregnant.

Experience with Neoral in pregnancy is very limited. The use of immunosuppressant medicines, including cyclosporin, during pregnancy has been shown to increase the risk of problems in the mother and the unborn child. If it is necessary for you to take this medicine, your doctor will discuss with you the benefits and risks of taking it during pregnancy.

Tell your doctor if you are breast-feeding.

Breast-feeding is not recommended since cyclosporin, the active ingredient in Neoral, passes into breast milk and may affect your baby.

Taking other 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.

Many other medicines may be affected by Neoral or they may affect how well Neoral works. This includes:

- St John's wort, an ingredient in many medicines that you can buy without a prescription from a pharmacy, health food shop or supermarket

- methotrexate, a medicine to treat severe rheumatoid arthritis, some types of cancers, and psoriasis
- antibacterial amino glycoside-type agents (e.g. gentamicin, tobramycin)
- antifungal agents containing amphotericin B
- antibacterial agents containing ciprofloxacin
- cytostatics containing melphalan
- agents used to treat urinary tract infection containing trimethoprim
- medicines used to treat pain (non-steroid anti-inflammatory drugs, e.g. diclofenac)
- acid secretion inhibitors of the H2-receptor antagonist type (e.g. cimetidine, ranitidine), which are used to reduce the amount of acid in your stomach
- other drugs which may affect the kidneys
- antibacterial agents of the macrolide type (e.g. clarithromycin, azithromycin, erythromycin)
- antifungal agents of the azole type (e.g. fluconazole, itraconazole, ketoconazole, voriconazole) or terbinafine
- oral contraceptives (Levonorgestrel and Norethisterone)
- protease inhibitors, used to treat or prevent infections caused by viruses
- imatinib, a medicine used to treat some cancers
- anthracycline anticancer medicines, such as doxorubicin
- certain blood pressure reducing agents of the calcium antagonist type (e.g. nifedipine, amlodipine, verapamil, diltiazem, amiodarone) or of the endothelin receptor antagonist type (e.g. bosentan, ambrisentan)
- certain anticonvulsives, used to prevent fits or seizures (e.g. carbamazepine, phenytoin)

- digoxin, a medicine used to treat heart failure
- colchicine, used to treat gout disease with painful, swollen joints
- HMG-CoA reductase inhibitors (statins), or fibric acid derivatives, which are used to treat high cholesterol
- prednisolone, a corticosteroid used to treat inflammatory diseases such as arthritis, asthma, colitis
- etoposide, used to treat cancer
- repaglinide, used to treat Type II diabetes
- aliskiren, used to treat high blood pressure
- potassium sparing drugs or potassium containing drugs
- ticlopidine (a medicine that is used after a stroke)
- octreotide, a medicine used to treat excess growth hormone, relieve the symptoms of certain types of cancer, or having surgery on the pancreas
- orlistat, used to help with weight loss
- danazol, a medicine used to treat menstrual disorders
- allopurinol, a medicine used to treat gout (a disease with painful, swollen joints caused by uric acid crystals)
- metoclopramide, a medicine used to prevent nausea and vomiting
- cholic acid and derivatives, which are used to treat gallstones
- tacrolimus, everolimus, or sirolimus, which are medicines that lower your immunity
- dabigatran, an anticoagulant medicine used to prevent stroke

You may need to take different amounts of your medicines or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking Neoral.

If you have not told your doctor about any of these things, tell him/her before you take Neoral.

How to take Neoral

Follow all directions given to you by your doctor and pharmacist carefully.

These instructions 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.

If you are changing from Sandimmun® to Neoral

Some patients who have been prescribed Neoral would have taken Sandimmun in the past. Like Neoral, Sandimmun contains the medicine, cyclosporin. Neoral, however, is designed to improve the way cyclosporin gets into your bloodstream. Because of this, your dose of Neoral may eventually be less than the dose of Sandimmun you used to take.

If you are changing from Sandimmun to Neoral, your doctor will perform some extra blood tests and then decide whether to change your dose of Neoral.

Do not change from Neoral to Sandimmun or from Sandimmun to Neoral unless it is under the strict supervision of your doctor.

Do not take Neoral and Sandimmun at the same time.

How much to take

The dose of Neoral is worked out for each person. It will depend on how much you weigh, what condition is being treated, how well Neoral works for you, and whether you have any side effects from this medicine. Your dose may be changed from time to time.

How to take it

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.

For full details on how to take Neoral oral solution, read the separate leaflet contained in the carton.

When to take it

Always take Neoral twice a day. It is best to take the doses 12 hours apart if possible. Take them at about the same time each day.

Taking your doses 12 hours apart and at the same time each day will have the best effect. It will also help you remember when to take them.

How long to take it

Keep taking this medicine for as long as your doctor recommends.

The length of treatment will depend on what medical condition you have.

For transplant patients:

you will need to take one or more immunosuppressant medicines for as long as you have the transplanted organ.

For nephrotic syndrome:

you may take Neoral for 3 months to start with. If it helps your condition, your doctor may decide to continue Neoral treatment for as long as it helps you and does not cause serious side effects.

For severe rheumatoid arthritis:

you will usually take Neoral for 3 months to start with. It may take this long to know whether Neoral will help your condition. If Neoral is effective, your doctor may then lower the dose and you will continue treatment at the lowest dose that is suitable for you.

For severe psoriasis:

you will usually take Neoral for up to 6 weeks to start with. If your condition improves, your doctor may want you to continue treatment at the lowest effective dose. You can only expect to benefit from this medicine while you continue to take it.

For severe atopic dermatitis:

you will usually take Neoral for up to 8 weeks to start with. Once your condition has improved, the dose may be slowly reduced, and in some cases, may even be stopped. Once you have stopped taking Neoral, your condition is likely to return, although this may take several weeks or months. Your doctor may then want you to start taking Neoral again.

If you forget to take it

If it is almost time for your next dose, skip the dose you missed and take the next dose when you are meant to.

Otherwise, take it as soon as you remember, and then go back to taking it as you would normally.

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

This may increase the chance of you getting an unwanted side effect.

If you miss more than one dose, contact your doctor as soon as possible.

If you have trouble remembering when to take your medicine, ask your pharmacist for some hints.

If you take too much (Overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone number 13 11 26), or go to Accident and Emergency at your nearest hospital if you think that you or anyone else may have taken too much Neoral. Do this even if there are no signs of discomfort or poisoning.

Keep the telephone numbers for these places handy.

While you are taking Neoral

Things you must do

Take Neoral exactly as your doctor has prescribed.

You must take this medicine exactly as prescribed so that it will work properly and to prevent unwanted side effects.

Make sure that you keep all of your doctor's appointments and have any tests done that are ordered by your doctor.

Your doctor may ask you to have tests from time to time to check how well your kidneys and liver are working. It may be necessary to measure the amount of cyclosporin, as well as the levels of other chemicals (eg. potassium) in your blood. Your blood pressure will also be checked regularly.

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

In some people taking Neoral, the amount of potassium in the blood can increase (called hyperkalaemia). The amount of potassium in the blood can also be increased by eating certain foods. Your doctor can tell you which foods to avoid.

If you become pregnant while taking Neoral, tell your doctor.

Your doctor can discuss with you the risks of taking it while you are pregnant.

If you develop lumps anywhere on/in your body, or develop any moles, or you notice changes in existing moles, tell your doctor.

This may be an early sign of a cancer. Immunosuppressant medicines, including Neoral, may increase the risk of developing certain cancers, including skin cancer and lymphoma (cancer of the lymphatic system).

Limit your exposure to sunlight and UV light. If you go out in the sun, wear a hat, appropriate protective clothing and a sunscreen with a high protection factor.

This will help to prevent the development of skin cancer.

If you have psoriasis or atopic dermatitis, you must be especially careful about developing skin cancer. Visit your skin specialist regularly for check-ups.

Take special care of your teeth and gums.

If you experience any symptoms of infection (e.g. fever, sore throat), inform your doctor immediately.

People taking immunosuppressant medicines are at a greater risk of getting infections. Taking good care of your teeth and gums will help to prevent dental and mouth infections.

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking Neoral.

Tell any other doctor, dentist or pharmacist who treats you that you are taking Neoral.

Things you must not do

Do not take Neoral with grapefruit or grapefruit juice since this can influence Neoral's effects.

Do not have any vaccinations without first checking with your doctor.

Some vaccines may be less effective or they may cause unwanted side effects while you are taking Neoral.

Do not give this medicine to anyone else even if their condition seems similar to yours.

Do not take it to treat any other complaints unless your doctor tells you to.

Things to be careful of

Be careful driving, operating machinery or doing jobs that require you to be alert while you are taking Neoral until you know how it affects you.

This medicine can cause tiredness, lack of energy or confusion in some people. If you have any of these symptoms, do not drive or do anything else that could be dangerous.

Neoral soft gelatin capsules and oral solution contain alcohol (ethanol). The capsules contain 11.8 vol. % alcohol, i.e. up to 500 mg per dose in the transplantation indications equivalent to 12.6 mL beer, 5 mL wine per dose. The oral solution contains 12.0 vol. % alcohol, i.e. up to 500 mg per dose in the transplantation indications equivalent to 12.6 mL beer, 5.3 mL wine per dose.

Alcohol may be harmful for those suffering from alcoholism, epilepsy, brain injury or liver disease as well as for pregnant or breast-feeding women and children.

Like other medicines that dampen the immune system, cyclosporin may influence your body's ability to fight against infection and may cause tumours or other malignancies, particularly of the skin.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Neoral, even if you do not think it is connected with the medicine.

All medicines can have side effects. Sometimes they are serious, but most of the time they are not. You may need medical treatment if you get some of the side effects. Your doctor may be able to relieve some of the side effects of Neoral by lowering the dose.

If you are over 65 years old, you should be especially careful while taking this medicine. Report any side effects promptly to your doctor.

As people grow older, they are more likely to get side effects from medicines.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor if you notice any of the following and they worry you:

- tiredness, lack of energy
- burning feeling in hands and feet, usually during the first week of treatment
- excessive growth of body and facial hair
- overgrown, thickened, swollen or bleeding gums
- stomach upset, including nausea (feeling sick), vomiting, loss of appetite, diarrhoea, stomach cramps, stomach ulcer
- tremor (shaking)
- headache, including migraine
- sensitivity to light
- weight loss or gain
- feeling depressed (sad)
- flushing of face, acne, darkening of skin
- painful menstrual periods or lack of periods
- increase in size of breasts in males and females

- muscle cramps, tenderness or weakness
- blocked or stuffy nose
- pain of lower extremities

The above side effects are not usually serious.

Tell your doctor immediately if you notice any of the following:

- fever (temperature above 37°C)
- constant "flu-like" symptoms such as chills, sore throat, aching joints, swollen glands, or any other signs of infection
- unusual bleeding or bruising
- signs of allergy such as rash, itching or hives on the skin; swelling of the face, lips, tongue or other part of the body; shortness of breath, wheezing or troubled breathing
- new lumps or moles, or changes to existing moles, anywhere on the body
- swelling of the eyelids, hands or feet due to excess fluid
- a change in the amount of urine passed or in the number of times you urinate, pain on urinating, bloody or smelly urine
- yellowing of the skin and/or eyes (jaundice) often accompanied by generally feeling unwell (for example, tiredness, lack of energy, loss of appetite, nausea and vomiting, pain in the abdomen)
- severe pain or tenderness in the stomach or abdomen
- vomiting blood or material that looks like coffee grounds; black sticky bowel motions or bloody diarrhoea
- unusual tiredness or weakness, which may be accompanied by dizziness, spots before the eyes, shortness of breath and pale skin
- numbness or "pins and needles" in the hands and feet
- a disturbance in brain function which may cause a variety of symptoms, including personality changes, confusion, disorientation, agitation, inability to sleep, decreased

responsiveness, weakness and loss of coordination in arms and legs with or without abnormal speech or eye movements, seizures (fits), clumsiness, memory loss, difficulty speaking or understanding what others say, visual hallucinations (seeing things that are not there) or other problems with vision, coma, paralysis of part or all of the body, stiff neck

- buzzing or ringing in the ears, difficulty hearing

The above are serious side effects that need medical attention.

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

- changes in kidney or liver function, or liver injury (with or without yellow eyes or skin)
- raised blood pressure
- increase in the amount of potassium or cholesterol in the blood
- decrease in the amount of magnesium in the blood
- increase in the amount of uric acid in the blood, which can lead to gout
- increase in blood sugar
- low white blood cell count
- low levels of red blood cells
- low levels of platelets in the blood

Your doctor will make sure that tests are done regularly to watch for these side effects.

Tell your doctor if you notice anything else that is making you feel unwell.

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

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

After using Neoral

Storage

Capsules:

- Keep your capsules in the foil blister pack until it is time to take them. If you take the capsules out of the blister pack, they will not keep well.
- Store the pack in a cool dry place where the temperature stays below 25°C.

Oral solution:

- Do not keep the bottle of oral solution in the fridge. Store it in a cool dry place, where the temperature stays between 20°C and 25°C. At low temperatures, the solution may start to go cloudy, or even start to set like a jelly. It will turn back to a liquid when kept at a warmer temperature. There may still be some small flakes in the liquid after it warms up. These flakes will not affect how Neoral works.
- Once the bottle has been opened, use the solution within 2 months. After that time, dispose of any solution that is left over.

Keep the medicine where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking Neoral or it has passed its expiry date, ask your pharmacist what to do with any medicine you have left over.

Product description

What it looks like

Neoral 10 mg capsules:

yellow-white, oval, soft gelatin capsules, printed in red with the

"NVR" and "10" in foil blister packs of 60.

Neoral 25 mg capsules:

blue-grey, oval, soft gelatin capsules, printed in red with the "NVR" and "25 mg;" in foil blister packs of 30.

Neoral 50 mg capsules:

yellow-white, oblong, soft gelatin capsules, printed in red with the "NVR" and "50 mg;" in foil blister packs of 30.

Neoral 100 mg capsules:

blue-grey, oblong, soft gelatin capsules, printed in red with the "NVR" and "100 mg;" in foil blister packs of 30.

Neoral oral solution:

clear, faintly yellow-brownish liquid in a 50 mL glass bottle, with a 1mL and 4mL syringe for measuring the dose.

Ingredients

Neoral capsules contain 10 mg, 25 mg, 50 mg or 100 mg of cyclosporin. Neoral oral solution contains cyclosporin 100 mg in each mL of solution.

The capsules and oral solution also contain:

- dl-alpha-tocopherol
- alcohol
- propylene glycol
- corn glycerides
- polyoxyl 40 hydrogenated castor oil

Neoral capsule shells contain:

- gelatin
- propylene glycol
- glycerol (E422)
- titanium dioxide (E171)
- iron oxide black CI 77499 (E172) (25 mg & 100 mg capsule shells only)

The printing ink on the capsules contains:

- carminic acid CI 75470 (E120)
- aluminium chloride
- sodium hydroxide
- hydroxypropyl methylcellulose 2910 [E464]

Sponsor

Neoral is supplied in Australia by:

NOVARTIS Pharmaceuticals
Australia Pty Limited
ABN 18 004 244 160
54 Waterloo Road
North Ryde NSW 2113
Telephone: 1 800 671 203
® = Registered Trademark

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 oral solution AUST R 49725

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