PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) - 1986

The medicine is dispensed with a doctor's prescription only

Sandimmun Neoral® 25 mg Capsules

Each capsule contains:
Ciclosporin 25 mg

Sandimmun Neoral® 50 mg Capsules

Each capsule contains:
Ciclosporin 50 mg

Sandimmun Neoral® 100 mg Capsules

Each capsule contains:
Ciclosporin 100 mg

Sandimmun Neoral® 100 mg/ml Oral Solution

Oral solution: Each 1 ml contains: Ciclosporin 100 mg

Inactive ingredients: see section 6 "Further information". Also see section "Important information regarding some of the ingredients of the medicine".

Read this leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.

This medicine has been prescribed for the treatment of your ailment. Do not pass it on to others. It may harm them even if it seems to you that their ailment is similar.

1. WHAT IS THE MEDICINE INTENDED FOR?

1. Prophylactic treatment for graft rejection in kidney, liver and heart transplantation, in combination with corticosteroids.
2. Treatment during a bone marrow transplantation.
3. Treatment of uveitis that is not from an infectious origin (Endogenous uveitis).
4. Treatment of nephrotic syndrome (Minimal Change Disease MCD type) when conventional therapy has failed.
5. Treatment of severe cases of rheumatoid arthritis when standard treatment is ineffective or inappropriate.
6. Treatment of severe cases of psoriasis in patients above 16 years of age that do not respond to other treatment.
7. Treatment of severe cases of atopic dermatitis in adults, for up to 8 weeks only, when conventional therapy is ineffective or inappropriate.

If you have undergone an organ or bone marrow transplantation, the function of Sandimmun Neoral is to control your body's immune system. Sandimmun Neoral prevents rejection of transplanted organs by blocking the development of special cells which would normally attack the transplanted tissue.

If you suffer from a non-transplant disease, where your body's own immune response attacks the cells in your body (autoimmune disease), Sandimmun Neoral suppresses immunoreactions in these diseases.

Therapeutic group: Immunosuppressants.

2. BEFORE USING THE MEDICINE

If you are taking Sandimmun Neoral after a transplant, the medicine will only be prescribed for you by a specialist experienced in transplants and/or autoimmune diseases. The information in this leaflet may change in accordance with the reason for which the medicine is being taken - after a transplant or for treatment of autoimmune diseases.

Follow your doctor's instructions exactly. They may be different than the general information in this leaflet.

Do not use the medicine if:

- you are allergic to ciclosporin or to any of the other ingredients of the medicine, listed in section 6.
- you are taking preparations containing *Hypericum perforatum* (St. John's wort).
- you are taking preparations containing *dabigatran etexilate* (to prevent blood clots after surgery) or *bosentan* and *aliskiren* (to treat hypertension).

If these conditions apply to you, **inform the doctor without taking Sandimmun Neoral.** If you are unsure, consult the doctor before starting treatment with Sandimmun Neoral.

Special warnings regarding use of the medicine:

Before and during treatment with Sandimmun Neoral, inform the doctor immediately:

- If you have signs of infection, such as fever or a sore throat. Sandimmun Neoral suppresses the immune system and may affect the ability of the body to fight infections.
- If you suffer from liver problems.
- If you suffer from kidney problems. Your doctor will carry out regular blood tests and may adjust the dosage if necessary.
- If you develop high blood pressure. Your doctor will check your blood pressure regularly and may give you a medicine to lower blood pressure if necessary.
- If you have low magnesium levels. Your doctor may give you magnesium supplements, especially after an organ transplant operation.
- If you have high blood potassium levels.
- If you suffer from gout.
- If you need to be vaccinated.

If these conditions apply to you before or during treatment with Sandimmun Neoral, refer to the doctor immediately.

Protection from sun exposure

Sandimmun Neoral suppresses the immune system. This increases the risk of developing cancers, particularly cancer of the skin and lymphatic system. Limit exposure to sunlight and UV light by wearing protective clothes and frequently applying sunscreen with a high protection factor.

Inform the doctor before starting treatment, if:

- you have or had problems related to alcohol dependence
- you have epilepsy
- you have any liver problems
- you are pregnant
- you are breastfeeding
- the medicine is given to a child

If these conditions apply to you (or if you are unsure), refer to the doctor before taking Sandimmun Neoral. This is because the medicine contains alcohol (ethanol). See section "Use of the medicine and alcohol consumption".

Tests during the course of treatment with Sandimmun Neoral

Your doctor will perform the following tests:

- **levels of ciclosporin in your blood** - especially if you have undergone a transplant.
- **blood pressure** before starting treatment and regularly during treatment.
- **liver and kidney function.**
- **blood lipid levels.**

If you have questions regarding how to use this medicine, or why this medicine has been prescribed for you, refer to the doctor.

If you are taking Sandimmun Neoral for a non-transplant disease (such as: uveitis, intermediary or posterior uveitis or Behçet's uveitis, atopic dermatitis, severe rheumatoid arthritis or nephrotic syndrome), do not take Sandimmun Neoral if you have:

- kidney problems (except for nephrotic syndrome)
- infections which are not under control with medication
- any type of cancer
- high blood pressure which is not under control with medication. If you develop high blood pressure during treatment and it cannot be controlled, your doctor must stop treatment with Sandimmun Neoral.

Do not take Sandimmun Neoral if any of the above conditions apply to you. If you are unsure, refer to the doctor or pharmacist before taking Sandimmun Neoral.
If you are being treated for Behçet's uveitis, the doctor will carefully monitor the course of treatment with Sandimmun Neoral, especially if you have neurological symptoms (for example: increased forgetfulness, personality changes noticed over time, psychiatric or mood disorders, "burning" sensation in the limbs, decreased sensation in the limbs, tingling sensation in the limbs, weakness of the limbs, walking disorders, headache with or without nausea and vomiting, vision disorders, including restricted movement of the eye).

If you are elderly and are being treated with Sandimmun Neoral for psoriasis or atopic dermatitis, avoid exposure to any type of UVB rays or phototherapy during the course of treatment. The doctor will closely monitor the course of treatment.

Children and adolescents
Do not give Sandimmun Neoral to children for a non-transplant disease, except for treatment of nephrotic syndrome.

Elderly population (65 years of age and older)
There is limited experience with administration of Sandimmun Neoral in elderly patients. Your doctor should monitor your kidney function. If you are over the age of 65 and have psoriasis or atopic dermatitis, you will only be treated with Sandimmun Neoral if your condition is particularly severe.

Drug interactions:
If you are taking, or have recently taken, other medicines, including non-prescription medicines or nutritional supplements, tell the doctor or pharmacist.
Inform the doctor or pharmacist before taking Sandimmun Neoral, particularly if you are taking:
- Medicines that may affect your potassium levels, such as medicines which contain potassium, potassium supplements, potassium-sparing diuretics and some medicines which lower your blood pressure.
- Methotrexate. This medicine is used to treat tumors, severe psoriasis and severe rheumatoid arthritis.
- Medicines which may increase or decrease the levels of ciclosporin (the active substance of Sandimmun Neoral) in the blood. The doctor might check the concentration of ciclosporin in your blood when starting or stopping treatment with other medicines.
  - Medicines which may increase the level of ciclosporin in your blood: antibiotics (such as erythromycin, azythromycin), anti-fungals (voriconazole, itraconazole), medicines used for heart problems or high blood pressure (such as: diltiazem, nicardipine, verapamil, amiodarone), metoclopramide (used to stop nausea), oral contraceptives, danazol (used to treat menstrual disorders), medicines used to treat gout (allopurinol), cholic acid and its derivatives (used to treat gallstones), protease inhibitors used to treat AIDS, imatinib (used to treat leukemia or tumors), colchicine, telaprevir (used to treat hepatitis C), cannabidiol (uses amongst others include treatment of seizures).
  - Medicines which may decrease the level of ciclosporin in your blood: barbiturates (medicines used to induce sleep), some anti-convulsants (such as carbamazepine, phenytoin), octreotide (used to treat acromegaly or neuroendocrine tumors in the gut), anti-bacterial medicines used to treat tuberculosis, orlistat (helps weight loss), herbal medicines containing St. John's wort, ticlopidine (used after a stroke), certain medicines which lower blood pressure (bosentan), and terbinafine (an anti-fungal medicine used to treat infections of the toes and nails).
- Other medicines which may affect the kidneys, such as: anti-bacterial medicines (gentamycin, tobramycin, ciprofloxacin), anti-fungal medicines which contain amphotericin B, medicines used for urinary tract infections which contain trimethoprim, medicines used to treat cancer which contain melphalan, medicines used to lower the amount of acid in the stomach (acid secretion inhibitors of the H2-receptor antagonist type), tacrolimus, pain killers (non-steroidal anti-inflammatory medicines such as diclofenac), fibric acid (used to lower fat in the blood).
- Nifedipine, used to treat high blood pressure and angina. Gum swelling that might spread toward the teeth may occur when taking nifedipine during the course of treatment with ciclosporin.
- Digoxin (used to treat heart problems), medicines which lower cholesterol (HMG-CoA reductase inhibitors also called statins), prednisolone, etoposide (used to treat cancer), repaglinide (an oral anti-diabetic preparation), immunosuppressants (everolimus, sirolimus), ambrisentan and specific anti-cancer medicines called anthracyclines (such as doxorubicin).

If any of these conditions apply to you (or you are unsure), refer to the doctor before taking Sandimmun Neoral.

Use of the medicine and food
Do not take Sandimmun Neoral with grapefruit or grapefruit juice, since this may affect the activity of the medicine.

Pregnancy and breastfeeding
Consult the doctor or pharmacist before taking this medicine. The doctor will discuss with you the potential risks of taking Sandimmun Neoral during pregnancy.
Tell the doctor if you are pregnant or intend to become pregnant. Experience with Sandimmun Neoral in pregnancy is limited. In general, Sandimmun Neoral should not be taken during pregnancy. If you must take this medicine, the doctor will discuss with you the benefits and potential risks associated with taking the medicine during pregnancy.
Tell the doctor if you are breastfeeding. Breastfeeding is not recommended during treatment with Sandimmun Neoral, since ciclosporin, the active substance in Sandimmun Neoral, passes into breast milk and may affect your baby.

Hepatitis C
Tell your doctor if you have hepatitis C. Your liver functions may change during hepatitis C treatment, which may affect the ciclosporin levels in your blood. Your doctor may have to carefully monitor the ciclosporin levels in your blood and adjust the dosage after you start hepatitis C treatment.

Driving and using machines
Sandimmun Neoral contains alcohol. This may affect your ability to drive or use machines.
In regards to children, they should be cautioned against riding bicycles or playing near the road, and the like.

Use of the medicine and alcohol consumption
Each Sandimmun Neoral 25 mg, 50 mg and 100 mg capsule contains 25 mg, 50 mg and 100 mg ethanol (alcohol), respectively, which is equivalent to 11.8% v/v.
Each ml of Sandimmun Neoral 100 mg/ml oral solution contains 94.70 mg ethanol (alcohol) which is equivalent to 12% v/v.
A 500 mg dose of Sandimmun Neoral contains a quantity of alcohol that is equivalent to approximately 13 ml beer or 5 ml wine. Such a small quantity of alcohol has no noticeable effect.

Important information about some of the ingredients in the medicine
Sandimmun Neoral contains castor oil.
Sandimmun Neoral contains castor oil, which may cause stomach discomfort and diarrhea.

Sandimmun Neoral contains propylene glycol.
This medicine contains 46.42 mg propylene glycol in each 25 mg capsule.
This medicine contains 90.36 mg propylene glycol in each 50 mg capsule.
This medicine contains 148.31 mg propylene glycol in each 100 mg capsule.
This medicine contains 94.70 mg propylene glycol in each ml oral solution.
If your baby is less than 4 weeks old, refer to the doctor or pharmacist before giving him this medicine, in particular if the baby is receiving other medicines that contain propylene glycol or alcohol.

Sandimmun Neoral contains sodium
This medicine contains less than 1 mmol sodium (23 mg) in each 25 mg, 50 mg and 100 mg capsule, i.e., it is essentially "sodium free".

3. HOW SHOULD YOU USE THE MEDICINE?
Always use according to the doctor's instructions. Check with the doctor or pharmacist if you are uncertain about the dosage and treatment regimen of the preparation.
Do not exceed the recommended dose.
The dosage of the medicine will be adjusted for you by the doctor only, according to your specific needs. A too high dosage may

affect the kidneys. Blood tests and hospital visits should be performed regularly, especially after a transplant. This will enable you to discuss the treatment with the doctor and to indicate the problems you experience.

The dosage and frequency of administration

The doctor will adjust the right dosage of Sandimmun Neoral for you, depending on your body weight and the reason you are taking the medicine. The doctor will also tell you how often to take the medicine.
Follow the doctor's instructions exactly, and never change the dosage on your own, even if you feel well.

If you were previously taking a different dosage form of oral ciclosporin:

The doctor will monitor the ciclosporin levels in your blood very closely for a short time following the switch from one oral dosage form to another.
When you switch from one oral ciclosporin dosage form to another, you may experience side effects. If this happens, please tell the doctor or pharmacist, as the dosage you are taking will have to be adjusted. **Never change** the dosage on your own, unless instructed to do so by the doctor.

Directions for use:

When to take Sandimmun Neoral

It is important to take the medicine at the same time every day, especially if you have undergone a transplant.

How to take Sandimmun Neoral

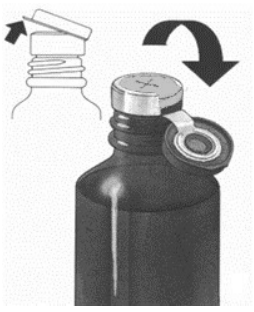
The daily dosage should always be taken in two separate doses.

Sandimmun Neoral capsules: remove the capsule from the blister. Swallow the capsules whole with a glass of water.

Sandimmun Neoral Oral Solution:

Initial use of Sandimmun Neoral Oral Solution:

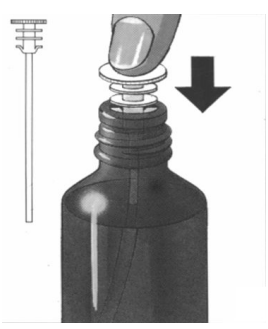
1. Raise the cap in the center of the metal sealing ring.



2. Completely remove the sealing ring.

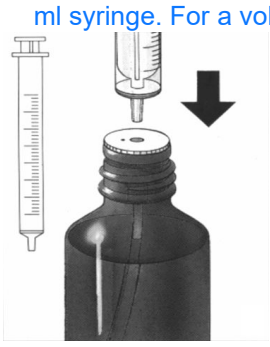
3. Take out the gray stopper **and throw it away**.

4. Push the tube unit with the white stopper firmly into the neck of the bottle.

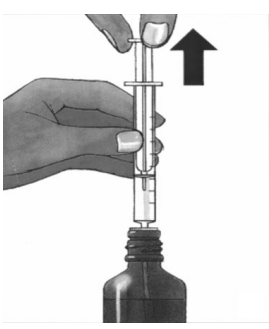


Measuring the dose

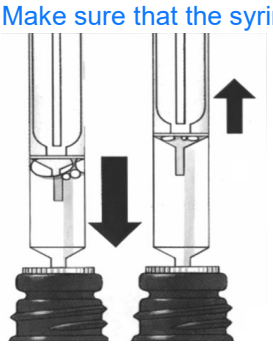
5. Choose a syringe depending on the volume prescribed by the doctor. For a volume less than 1 ml or equal to 1 ml, use the 1-ml syringe. For a volume greater than 1 ml, use the 4-ml syringe. Insert the nozzle of the syringe into the white stopper.



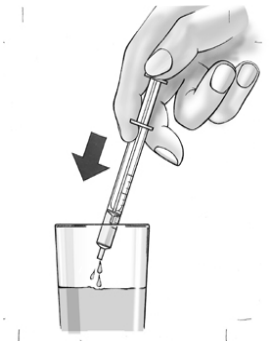
6. Pull out the plunger until the volume of solution prescribed by the doctor has been drawn up (position the lower part of the plunger in front of the graduation corresponding to the volume prescribed by the doctor).



7. Expel large bubbles by depressing and withdrawing the plunger a few times before removing the syringe containing the prescribed dosage from the bottle. The presence of a few tiny bubbles is of no importance and will not affect the dosage in any way.
   Make sure that the syringe has the right amount of medicine and then remove the syringe from the bottle.



8. Pour the solution from the syringe into a small glass that contains a bit of liquid, preferably orange juice or apple juice (but not grapefruit juice). Avoid any contact between the syringe and the liquid in the glass. Stir and drink the entire mixture right away.



9. After use, wipe the syringe on the outside only with a dry tissue and put it back in its cover. The tube and the white stopper should remain in the bottle. Close the bottle with the separately provided cap.

Subsequent use of the oral solution:
Start from step 5.

Duration of treatment
The doctor will tell you how long you will need to take Sandimmun Neoral. This depends on whether the reason for the treatment is after a transplant or for the treatment of a severe skin disease, rheumatoid arthritis, uveitis or nephrotic syndrome. For severe rash, the treatment usually lasts for 8 weeks.
Keep taking Sandimmun Neoral for as long as your doctor tells you.
If you have questions about how long to take Sandimmun Neoral, refer to the doctor or pharmacist.

If you accidentally took a higher dosage
If you took an overdose, or if a child has accidentally swallowed the medicine, refer immediately to a doctor or proceed to a hospital emergency room, and bring the package of the medicine with you. You may need medical treatment.

If you forgot to take the medicine
If you forgot to take this medicine at the scheduled time, take a dose as soon as you remember, unless it is almost time for the next dose. Continue taking the medicine as usual. Never take two doses together!

If you stop taking the medicine
Adhere to the treatment regimen as recommended by the doctor.
Do not stop treatment with Sandimmun Neoral without instruction from the doctor. Continue treatment even if you feel well. Stopping Sandimmun Neoral treatment may increase the risk of rejection of the transplanted organ.

Do not take medicines in the dark! Check the label and the dose each time you take the medicine. Wear glasses if you need them.

If you have further questions regarding use of the medicine, consult the doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Sandimmun Neoral may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

Some side effects could be serious:

Refer to a doctor immediately if you notice any of the following serious side effects:

- Like other medicines that suppress the immune system, ciclosporin may influence your body's ability to fight against infections and may cause tumors or other cancers, particularly of the skin. Signs of infection might be fever or sore throat.
- If you experience changes in vision, loss of coordination, clumsiness, memory loss, difficulty speaking or understanding what other people say, and muscle weakness; these might be symptoms of an infection of the brain called progressive multifocal leukoencephalopathy (PML).
- Brain disorders with signs such as: seizures, confusion, disorientation, reduced responsiveness, personality changes, agitation, sleeplessness, vision disorders, blindness, coma, paralysis of part or all of the body, stiff neck, loss of coordination with or without abnormal speech or eye movements.
- Swelling at the back of the eye that may be associated with blurred vision and may cause a vision disorder because of increased pressure inside the head (benign intracranial hypertension).
- Liver problems and damage with or without yellowing of the skin and eyes, nausea, loss of appetite and dark urine.
- Kidney disorders, which may greatly reduce urine output.
- Low level of red blood cells or platelets. The signs include pale skin, tiredness, breathlessness, dark urine (a sign of the breakdown of red blood cells), bruising or bleeding for no obvious reason, confusion, disorientation, reduced alertness and kidney problems.

Additional side effects

Very common side effects - may affect more than 1 in every 10 patients:
Kidney disorders, high blood pressure, headache, involuntary shaking of the body, excessive growth of body and facial hair, high level of lipids in the blood.
If any of these side effects affect you severely, **refer to the doctor.**

Common side effects - may affect between 1 and 10 in every 100 patients:
Seizures, liver disorders, high level of sugar in the blood, tiredness, loss of appetite, nausea, vomiting, abdominal discomfort or abdominal pain, diarrhea, excessive hair growth, acne, hot flushes, fever, low level of white blood cells, numbness or tingling, muscle pain, muscle spasm, stomach ulcer, overgrowth (swelling) of the gums until they cover the teeth, high level of uric acid or potassium in the blood, low level of magnesium in the blood.
If any of these side effects affect you severely, **refer to the doctor.**

Uncommon side effects - may affect between 1 and 10 in every 1,000 patients:
Symptoms of brain disorders including sudden fits, mental confusion, sleeplessness, disorientation, vision disorders, unconsciousness, weakness in the limbs, impaired movements.
In addition, rash, general swelling, weight gain, low level of red blood cells, low level of platelets in the blood that may increase the risk of bleeding.
If any of these side effects affect you severely, **refer to the doctor.**

Rare side effects - may affect between 1 and 10 in every 10,000 patients:
Nerve disorder, with feeling of numbness or tingling in the fingers and toes, inflammation of the pancreas with severe upper stomach pain, muscle weakness, loss of muscle strength, pain in muscles of the legs, hands or anywhere in the body, destruction of red blood cells, involving kidney problems with symptoms such as swelling of the face, stomach, hands and/or feet; decreased urination, breathing difficulties, chest pain, fits (seizures), unconsciousness, abnormal changes in the menstrual cycle, breast enlargement in men.
If any of these side effects affect you severely, **refer to the doctor.**

Very rare side effects - may affect between 1 and 10 in every 100,000 patients:
Swelling at the back of the eye which may be associated with an increase in pressure inside the head and vision disorders.
If this side effect affects you severely, **refer to the doctor.**

Side effects of unknown frequency - the frequency cannot be estimated from the available data:
Serious liver problems, with or without yellowing of the eyes or skin, nausea, loss of appetite, dark colored urine, swelling of the face, stomach, feet, hands or the whole body; bleeding underneath the skin or purple skin patches, sudden bleeding with no apparent cause; migraine or severe headache often with nausea, vomiting and sensitivity to light; pain in the legs and feet, hearing impairment.
If any of these side effects affect you severely, **refer to the doctor.**

If a side effect occurs, if one of the side effects worsens or if you suffer from a side effect not mentioned in the leaflet, consult with the doctor.

Additional side effects in children and adolescents:
There are no additional side effects expected in children and adolescents when compared with adults.

Reporting side effects
Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link:
https://sideeffects.health.gov.il

5. HOW SHOULD THE MEDICINE BE STORED?

- Avoid poisoning! This medicine and any other medicine must be kept in a safe place out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting without explicit instruction from the doctor.
- Do not use this medicine after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month.
- Do not use the medicine if you notice that the package is damaged or has signs of tampering.
- Do not discard the medicine in the waste bin or sink. Consult with the pharmacist regarding how to dispose of a medicine you no longer need. This will help to protect the environment.

Sandimmun Neoral Oral Solution:
Store the oral solution at room temperature, between 15°C-30°C **and not** in the refrigerator, as it contains oils, which solidify at low temperatures. Below 20°C, a jelly-like formation may occur. If the jelly-like appearance does not disappear after warming up to 30°C, do not use Sandimmun Neoral oral solution. Small flakes or small amounts of sediment may still be observed. If the oral solution is stored by mistake in the refrigerator, it should reach room temperature before it can be used again. Flakes or sediment are of no importance to the medicine's effectiveness or safety, and measuring with the dosing syringe will still be accurate.
After opening the bottle, use the solution within 2 months.

Sandimmun Neoral Capsules:
Store at a temperature that does not exceed 25°C. Keep in the original package in order to protect from moisture.
Keep the capsules in the package and only remove them immediately before use.
When a package is opened, a characteristic smell is noticeable. This is normal and does not indicate that there is any problem with the capsules.

6. FURTHER INFORMATION

Capsules:

Capsules content:
macrogolglycerol hydroxystearate / polyoxyl 40 hydrogenated castor oil, corn oil–mono–di–triglycerides, ethanol anhydrous / alcohol dehydrated, propylene glycol, alpha–tocopherol.
Sandimmun Neoral soft gelatin capsules contain 11.8% v/v ethanol (9.4% w/v).

Capsule shell:
gelatin, propylene glycol, glycerol 85%, titanium dioxide (E 171),

iron oxide black (E 172) (25- and 100-mg capsules).

Capsule color:
carminic acid (E 120), aluminium chloride hexahydrate, sodium hydroxide, propylene glycol, hypromellose / hydroxypropyl methylcellulose 2910, isopropanol / isopropyl alcohol, water, purified.

Oral Solution:
polyoxyl 40 hydrogenated castor oil, corn oil-mono–di–triglycerides, propylene glycol, ethanol absolute, DL–alpha–tocopherol.
Sandimmun Neoral oral solution contains 12% v/v ethanol (9.5% w/v).

What the medicine looks like and the contents of the package

Capsules:
Sandimmun Neoral 25 mg - a soft gelatin, oval, blue-gray capsule, with imprint NVR 25mg in red ink.
Sandimmun Neoral 50 mg - a soft gelatin, oblong, yellow-white capsule, with imprint NVR 50mg in red ink.
Sandimmun Neoral 100 mg - a soft gelatin, oblong, blue-gray capsule, with imprint NVR 100mg in red ink.
Each pack contains 50 capsules in trays.

Oral Solution:
Sandimmun Neoral 100 mg/ml Oral Solution - 50 ml of a clear, yellow to light yellow or brown-yellow to light brown-yellow solution.
The oral solution pack contains:
1. An oral solution in a glass bottle.
2. Two plastic oral dispenser sets:
- A set containing a tubing unit with a white cap and a 1 ml syringe for measuring the dose. The 1 ml syringe is used to measure doses smaller than or equal to 1 ml (each 0.05 ml mark is equivalent to 5 mg ciclosporin).
- A set containing a tubing unit with a white cap and a 4 ml syringe for measuring the dose. The 4 ml syringe is used to measure doses larger than 1 ml, and up to 4 ml (each 0.1 ml mark is equivalent to 10 mg ciclosporin).

3. A black cap for closing the bottle again after first opening.

Revised in February 2023 according to MOH guidelines.

Registration Holder and Importer and its Address:
Novartis Israel Ltd., P.O.B 7126, Tel Aviv.

Registration numbers of the medicine:
Sandimmun Neoral 25 mg Capsules 066 67 28138
Sandimmun Neoral 50 mg Capsules 066 77 28139
Sandimmun Neoral 100 mg Capsules 066 78 28140
Sandimmun Neoral 100 mg/ml Oral Solution
066 79 28141