NOVARTIS

SANDIMMUN® Ampoules 50 mg/mL

Ciclosporin

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SANDIMMUN® Ampoules 50 mg/mL

Read all of this leaflet carefully before you start taking this medicine

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

What is in this leaflet

1. What SANDIMMUN is and what it is used for

2. What you need to know before you take SANDIMMUN

3. How to take SANDIMMUN

4. Possible side effects

5. How to store SANDIMMUN

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1. What SANDIMMUN is and what it is used for

What SANDIMMUN is

The name of your medicine is SANDIMMUN. It contains the active substance ciclosporin. The concentrate is used to prepare a solution which is administered by intravenous infusion. This belongs to a group of medicines known as immunosuppressive agents. These medicines are used to lower the body's immune reactions.

What SANDIMMUN is used for and how SANDIMMUN works

- **If you have had an organ transplant and bone marrow transplantation**, the function of SANDIMMUN is to control your body's immune system. SANDIMMUN prevents rejection of transplanted organs by blocking the development of certain cells which would normally attack the transplanted tissue.
- **If you have an autoimmune disease**, in which your body's immune response attacks your body's own cells, SANDIMMUN stops this immune reaction. Such diseases include severe cases of certain skin diseases (atopic dermatitis, or eczema and psoriasis) and severe rheumatoid arthritis.

2. What you need to know before you take SANDIMMUN

If you are taking SANDIMMUN following a transplant it will only be prescribed for you by a doctor with experience in transplants and/or autoimmune diseases.

The advice in this leaflet may vary depending on whether you are taking the medicine for a transplant or for an autoimmune disease.

Follow all your doctor's instructions carefully. They may differ from the general information contained in this leaflet.

Do not take SANDIMMUN:

- if you are allergic to ciclosporin or any of the other ingredients of this medicine (listed in section 6).

Do not take SANDIMMUN and **tell your doctor** if the above applies to you. If you are not sure, talk to your doctor before taking SANDIMMUN.

Warnings and precautions

Before and during treatment with SANDIMMUN, tell your doctor straight away:

- if you have any signs of infection, such as fever or a sore throat. SANDIMMUN suppresses the immune system and may also affect your body's ability to fight against infection.
- if you have liver problems.

- if you have kidney problems. Your doctor will carry out regular blood tests and may change your dose 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 levels of magnesium in your body. Your doctor may give you magnesium supplements to take, especially just after your operation if you have had a transplant.
- if you have high levels of potassium in your blood.
- if you have gout.
- if you need to have a vaccination.

If any of the above applies to you before or during treatment with SANDIMMUN, tell your doctor straight away.

Sunlight and sun protection

SANDIMMUN suppresses your immune system. This increases your risk of developing cancers, particularly of the skin and lymphoid system. You should limit your exposure to sunlight and UV light by:

- Wearing appropriate protective clothing.
- Often applying a sunscreen with a high protection factor.

Talk to your doctor before taking SANDIMMUN:

- if you have or have had alcohol-related problems.
- if you have epilepsy.
- if you have any liver problems.
- if you are pregnant.
- if you are breast-feeding.
- if this medicine is being prescribed for a child.

If any of the above apply to you (or you are not sure), tell your doctor before taking SANDIMMUN. This is because this medicine contains alcohol (see section below "SANDIMMUN contains ethanol").

Monitoring during your treatment with SANDIMMUN

Your doctor will check:

- **the levels of ciclosporin in your blood,** especially if you have had a transplant,
- your **blood pressure** before the start of your treatment and regularly during treatment,
- how well your **liver and kidneys** are working,
- your **blood lipids (fats).**

If you have any questions about how SANDIMMUN works or why this medicine has been prescribed for you, ask your doctor.

In addition, if you are taking SANDIMMUN for a non-transplant disease (atopic dermatitis or severe rheumatoid arthritis), do not take SANDIMMUN:

- if you have kidney problems.
- if you have an infection which is not under control with medication.
- if you have any type of cancer.
- if you have high blood pressure (hypertension) which is not under control with medication. If you get high blood pressure during treatment and it cannot be controlled, SANDIMMUN should be stopped by your doctor.

Do not take SANDIMMUN if any of the above applies to you. If you are not sure, talk to your doctor or pharmacist before taking SANDIMMUN.

Your doctor will closely monitor you if you are elderly and are being treated for psoriasis or atopic dermatitis.

If you have been prescribed SANDIMMUN to treat your psoriasis or atopic dermatitis, you must not be exposed to any UVB-rays or phototherapy during treatment.

Children and adolescents

SANDIMMUN should not be given to children for a non-transplant disease.

Elderly population (65 years of age and older)

There is limited experience with SANDIMMUN in elderly patients. Your doctor should monitor how well your kidneys work. If you are over 65 and have psoriasis or atopic dermatitis, you should only be treated with SANDIMMUN if your condition is particularly severe.

Other medicines and SANDIMMUN

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

In particular, tell your doctor or pharmacist if you are taking any of the following medicines before or during SANDIMMUN treatment:

- Medicines that may affect your potassium levels. These include medicines which contain potassium, potassium supplements, water tablets (diuretics) called potassium-sparing diuretics and some medicines which lower your blood pressure.
- Methotrexate. This is used to treat tumours, severe psoriasis and severe rheumatoid arthritis.
- Medicines which may increase or decrease the level of ciclosporin (the active substance of SANDIMMUN) in your blood. Your doctor might check the level of

ciclosporin in your blood when starting or stopping treatment with other medicines.

- Medicines which may increase the level of ciclosporin in your blood include: antibiotics (such as erythromycin or azythromycin), anti-fungals (voriconazole, itraconazole), medicines used for heart problems or high blood pressure (diltiazem, nicardipine, verapamil, amiodarone), metoclopramide (used to stop sickness), oral contraceptives, danazol (used to treat menstrual problems), medicines used to treat gout (allopurinol), cholic acid and derivatives (used to treat gallstones), protease inhibitors used to treat HIV, imatinib (used to treat leukaemia or tumours), 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 include: barbiturates (used to help you to sleep), some anti-convulsant medicines (such as carbamazepine or phenytoin), octreotide (used to treat acromegaly or neuroendocrine tumours in the gut), anti-bacterial medicines used to treat tuberculosis, orlistat (used to help 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).

- Medicines which may affect your kidneys. These include: anti-bacterial medicines (gentamycin, tobramycin, ciprofloxacin), anti-fungal medicines which contain amphotericin B, medicines used for urinary tract infections which contain trimethoprim, medicines for cancer which contain melphalan, medicines used to lower the amount of acid in your stomach (acid secretion inhibitors of the H2-receptor antagonist type), tacrolimus, pain killers (non-steroid anti- inflammatory medicines such as diclofenac), fibric acid medicines (used to lower the amount of fat in the blood).
- Nifedipine. This is used to treat high blood pressure and heart pain. You might get swollen gums that might grow over your teeth if you are taking nifedipine during your 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 (oral antidiabetic medicine), immunosuppressives (everolimus, sirolimus), ambrisentan and specific anticancer medicines called anthracyclines (such as doxorubicin).

If any of the above applies to you (or you are not sure), talk to your doctor or pharmacist before taking SANDIMMUN.

SANDIMMUN with food and drink

Do not take SANDIMMUN with grapefruit or grapefruit juice. This is because these can affect how SANDIMMUN works.

Pregnancy and breast-feeding

Ask your doctor or pharmacist for advice before taking this medicine. Your doctor will discuss with you the potential risks of taking SANDIMMUN during pregnancy.

- **Tell your doctor if you are pregnant or intend to become pregnant.** Experience with SANDIMMUN in pregnancy is limited. In general, SANDIMMUN should not be taken during pregnancy. If it is necessary for you to take this medicine, your doctor will discuss with you the benefits and potential risks of taking it during pregnancy.
- **Tell your doctor if you are breast-feeding.** Breast-feeding is not recommended during treatment with SANDIMMUN. This is because ciclosporin, the active substance, passes into breast milk. This may affect your baby.

Hepatitis C

Tell your doctor if you have hepatitis C. Your liver function may change with treatment of hepatitis C and this may affect the levels of ciclosporin in your blood. Your doctor may need to closely monitor ciclosporin blood levels and make adjustments to the dose after you start treatment for hepatitis C.

Driving and using machines

SANDIMMUN contains alcohol. This may affect your ability to drive and use machines.

SANDIMMUN contains ethanol

SANDIMMUN concentrate for solution for infusion contains 34.4 v/v ethanol (27.8 w/v). A 100 mg dose of SANDIMMUN concentrate contains 545 mg ethanol equivalent to about 14 mL of beer or 6 mL of wine.

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.

SANDIMMUN concentrate for solution for infusion contains castor oil which may cause severe allergic reactions.

3. How to take SANDIMMUN

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

Always take SANDIMMUN exactly as your doctor has told you. Check with your doctor if you are not sure.

How much SANDIMMUN concentrate for solution for infusion you will be given

Your doctor will work out the correct dose of SANDIMMUN for you. This depends on your body weight and what you are being given the medicine for.

- The total dose each day is usually between 3 to 5 mg per kilogram of your weight. This is divided into two doses.
- Usually, higher doses are used before and just after your transplant. Lower doses are used once your transplanted organ or bone marrow has stabilised.
- Your doctor will adjust your dose to one that is ideal for you. To do this, your doctor may need to do some blood tests.

How SANDIMMUN concentrate for solution for infusion will be used

The medicine will be diluted before use 1:20 to 1:100 with saline or 5 % glucose and then given to you by slow infusion over approximately 2 to 6 hours. Diluted medicine must be thrown away after 24 hours.

How long SANDIMMUN concentrate for solution for infusion will be used

You will be switched to ciclosporin in the form of capsules or oral solution (both of which are taken by mouth) as soon as possible.

If you have been given more SANDIMMUN concentrate for solution for infusion than you should

Too much of the medicine can affect your kidneys. You will have regular blood tests and visits to the hospital. This will give you the chance to talk to your doctor about your treatment and talk about any problems you may be having.

4. Possible side effects

SANDIMMUN can have side effects.

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

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

Some side effects could be serious

Tell your doctor straight away if you notice any of the following serious side effects:

- Like other medicines that act on the immune system, ciclosporin may influence your body’s ability to fight against infection and may cause tumours or other cancers, particularly of the skin. Signs of infection might be fever or sore throat.

- Changes in your sight, loss of coordination, being clumsy, memory loss, difficulty speaking or understanding what others say, and muscle weakness. These might be signs of an infection of the brain called progressive multifocal leukoencephalopathy.
- Brain problems with signs such as seizures, confusion, feeling disorientated, being less responsive, personality changes, feeling agitated, sleeplessness, changes to your sight, blindness, coma, paralysis of part or all of the body, stiff neck, loss of coordination with or without unusual speech or eye movements.
- Swelling at the back of the eye. This may be associated with blurred vision. It may also affect your sight because of the higher pressure inside your head (benign intracranial hypertension).
- Liver problems and damage with or without yellow skin and eyes, nausea, loss of appetite and dark urine.
- Kidney problems which may greatly reduce the amount of urine you produce.
- Low level of red blood cells or platelets. The signs include pale skin, feeling tired, being breathless, having dark urine (this is a sign of the breakdown of red blood cells), bruising or bleeding with no obvious reasons, feeling confused, feeling disorientated, being less alert and having kidney problems.

Other side effects include:

Very common side effects: *These side effects may affect more than 1 in 10 people.*

- Kidney problems.
- High blood pressure.
- Headache.
- Shaking of your body which you cannot control.
- Excessive growth of body and facial hair.
- High level of lipids in your blood.

If any of these affects you severely, **tell your doctor.**

Common side effects: *These side effects may affect between 1 and 10 in every 100 people.*

- Fits (seizures).
- Liver problems.
- High level of sugar in your blood.
- Tiredness.
- Loss of appetite.
- Nausea (feeling sick), vomiting, abdominal pain, constipation, diarrhoea.
- Excessive hair growth.
- Acne, hot flushes.
- Fever.

- Low level of white blood cells.
- Feeling numb or tingling.
- Pain in your muscles, muscle spasm.
- Stomach ulcer.
- Gum tissue overgrowing and covering your teeth.
- High level of uric acid or potassium in your blood, low levels of magnesium in your blood.

If any of these affects you severely, **tell your doctor.**

Uncommon side effects: *These side effects may affect between 1 and 10 in every 1,000 people.*

- Symptoms of brain disorders including sudden fits, mental confusion, sleeplessness, disorientation, disturbance of vision, unconsciousness, sense of weakness in the limbs, impaired movements.
- Rash.
- General swelling.
- Weight gain.
- Low level of red blood cells, low level of platelets in your blood which could increase the risk of bleeding.

If any of these affects you severely, **tell your doctor.**

Rare side effects: *These side effects may affect between 1 and 10 in every 10,000 people.*

- Nerve problems with numbness or tingling in fingers and toes.
- Inflammation of the pancreas with severe upper stomach pain.
- Muscle weakness, loss of muscle strength, pain in muscles of the legs or 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 difficulty, chest pain, fits, unconsciousness.
- Changes in menstrual cycle, breast enlargement in men.

If any of these affects you severely, **tell your doctor.**

Very rare side effects: *These side effects may affect between 1 and 10 in every 100,000 people.*

- Swelling at the back of the eye which may be associated with an increase in pressure inside the head and eyesight disturbances.

If this affects you severely, **tell your doctor.**

Other side effects with frequency not known: *Frequency cannot be estimated from the available data.*

- Serious liver problems both with and without yellowing of the eyes or skin, nausea (feeling sick), loss of appetite, dark coloured urine, swelling of the face, feet, hands and/or the whole body.
- Bleeding underneath the skin or purple skin patched, sudden bleeding with no apparent cause.
- Migraine or severe headache often with feeling and being sick (nausea, vomiting) and being sensitive to light.
- Pain in legs and feet.

If any of these affects you severely, **tell your doctor.**

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

Additional side effects in children and adolescents

There are no additional side effects to be expected in children and adolescents compared to adults.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the “6.04 Adverse Drug Reaction Reporting Form”, found

online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8.

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

5. How to store SANDIMMUN

KEEP OUT OF THE REACH OF CHILDREN

- This medicine does not require any special temperature storage conditions.
- Store in the original package.
- Once an ampoule has been opened, the contents should be used immediately.
- Following dilution, the solution should be used immediately and discarded after 24 hours.

Do not use SANDIMMUN after the expiry date shown on the pack

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What SANDIMMUN concentrate for solution for infusion contains

- The active substance is ciclosporin. One mL of the concentrate for solution for infusion contains 50 mg ciclosporin.
- The other ingredients are: ethanol anhydrous, castor oil polyoxyl.

What SANDIMMUN concentrate for solution for infusion looks like and contents of the pack

A clear brown-yellow, oily solution in a 1 mL clear glass ampoule coded with a yellow-coloured ring and a blue-coloured ring on the neck of the ampoule. Carton of 10 ampoules of 1 mL each.

Holder of Certificate of Registration

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