Lexicomp®

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(For additional information <u>see "Cyclosporine (ciclosporin) (systemic): Drug information"</u> and <u>see "Cyclosporine (ciclosporin) (systemic): Pediatric drug information"</u>)

You must carefully read the "Consumer Information Use and Disclaimer" below in order to understand and correctly use this information.

Brand Names: US

Gengraf; Neoral; SandIMMUNE

Brand Names: Canada

APO-CycloSPORINE; Neoral; SandIMMUNE IV; SANDOZ CycloSPORINE

Warning

All products:

- You may have more of a chance of getting an infection. Wash hands often. Stay away from people with infections, colds, or flu. Some infections have been very bad and even deadly.
- Lymphoma and other cancers have happened in people who take this drug or drugs like it. This has been deadly in some cases. Talk with the doctor.
- If this drug is given with other drugs that work on the immune system, it can add to the chance of getting an infection or lymphoma or other cancers. Call your doctor right away if you have a change in color or size of a mole; a lump in the armpit, groin, or neck; or any new or changing skin lump or growth. Talk with the doctor.
- Call your doctor right away if you have any signs of infection like fever, chills, flu-like signs, very bad sore throat, ear or sinus pain, cough, more sputum or change in color of sputum, pain with passing urine, mouth sores, or a wound

that will not heal.

- This drug may cause kidney problems in some patients. Talk with the doctor.
- High blood pressure has happened with this drug. Have your blood pressure checked as you have been told by your doctor.
- Have blood work checked as you have been told by the doctor. Talk with the doctor.
- There are different brands and forms of this drug. Do not switch between different brands or forms of this drug without calling the doctor who ordered it.

Sandimmune®:

• This drug may be given with steroid drugs like hydrocortisone. Do not use with other drugs that weaken the immune system. Talk with the doctor.

Gengraf® or Neoral®:

• If you are taking this drug for psoriasis AND you have used other drugs or radiation to treat this health problem before, your chance of skin cancer may be higher.

What is this drug used for?

- It is used to keep the body from harming the organ after an organ transplant.
- It is used to treat rheumatoid arthritis.
- It is used to treat psoriasis.
- It may be given to you for other reasons. Talk with the doctor.

What do I need to tell my doctor BEFORE I take this drug?

For all patients taking this drug:

- If you have an allergy to cyclosporine or any other part of this drug.
- If you are allergic to this drug; any part of this drug; or any other drugs, foods, or substances. Tell your doctor about the allergy and what signs you had.

- If you have any of these health problems: Cancer, kidney problems, or high blood pressure.
- If you are taking any of these drugs: Aliskiren, amiloride, bosentan, dabigatran, orlistat, spironolactone, or triamterene.
- If you are breast-feeding or plan to breast-feed.

Psoriasis:

• If you have psoriasis and are using other treatments like other drugs or radiation.

This is not a list of all drugs or health problems that interact with this drug. This drug interacts with many other drugs. The chance of severe, lifethreatening, or deadly side effects may be raised. Tell your doctor and pharmacist about all of your drugs (prescription or OTC, natural products, vitamins) and health problems. You must check to make sure that it is safe for you to take this drug with all of your drugs and health problems. Do not start, stop, or change the dose of any drug without checking with your doctor.

What are some things I need to know or do while I take this drug?

- Tell all of your health care providers that you take this drug. This includes your doctors, nurses, pharmacists, and dentists.
- If you have high blood sugar (diabetes), you will need to watch your blood sugar closely.
- If you are taking a salt substitute that has potassium in it, a potassium-sparing diuretic, or a potassium product, talk with your doctor.
- This drug has alcohol in it. Talk with the doctor.
- The chance of skin cancer may be raised. Avoid lots of sun, sunlamps, and tanning beds. Use sunscreen and wear clothing and eyewear that protects you from the sun.
- Have your skin checked as you have been told by your doctor.
- Some people treated with this drug have had very bad kidney problems caused

by a certain viral infection (BK virus). In people who have had a kidney transplant, BK virus infection may cause loss of the kidney. Call your doctor right away if you have signs of kidney problems like change in the amount of urine passed, difficulty or pain when passing urine, or blood in the urine.

- A very bad and sometimes deadly brain problem called posterior reversible encephalopathy syndrome (PRES) has happened with this drug. Call your doctor right away if you have signs like feeling confused, lowered alertness, change in eyesight, loss of eyesight, seizures, or very bad headache.
- Talk with your doctor before getting any vaccines. Use of some vaccines with this drug may either raise the chance of an infection or make the vaccine not work as well.
- Take good care of your teeth. See a dentist often.
- Avoid grapefruit and grapefruit juice.
- Watch for gout attacks.
- If you are 65 or older, use this drug with care. You could have more side effects.
- Use with care in children. Talk with the doctor.
- This drug may cause harm to the unborn baby if you take it while you are pregnant. If you are pregnant or you get pregnant while taking this drug, call your doctor right away.

What are some side effects that I need to call my doctor about right away?

WARNING/CAUTION: Even though it may be rare, some people may have very bad and sometimes deadly side effects when taking a drug. Tell your doctor or get medical help right away if you have any of the following signs or symptoms that may be related to a very bad side effect:

 Signs of an allergic reaction, like rash; hives; itching; red, swollen, blistered, or peeling skin with or without fever; wheezing; tightness in the chest or throat; trouble breathing, swallowing, or talking; unusual hoarseness; or swelling of the mouth, face, lips, tongue, or throat.

- Signs of high blood pressure like very bad headache or dizziness, passing out, or change in eyesight.
- Signs of kidney problems like unable to pass urine, change in how much urine is passed, blood in the urine, or a big weight gain.
- Signs of electrolyte problems like mood changes, confusion, muscle pain or weakness, a heartbeat that does not feel normal, seizures, not hungry, or very bad upset stomach or throwing up.
- Any unexplained bruising or bleeding.
- Feeling very tired or weak.
- A burning, numbness, or tingling feeling that is not normal.
- Chest pain or pressure or a fast heartbeat.
- · Gum changes.
- Hearing loss.
- · Shortness of breath.
- Shakiness.
- Swelling.
- Very bad and sometimes deadly liver problems have happened with this drug.
 Call your doctor right away if you have signs of liver problems like dark urine, feeling tired, not hungry, upset stomach or stomach pain, light-colored stools, throwing up, or yellow skin or eyes.
- A very bad brain problem called progressive multifocal leukoencephalopathy
 (PML) has happened with this drug. It may cause disability or can be deadly. Tell
 your doctor right away if you have signs like confusion, memory problems, low
 mood (depression), change in the way you act, change in strength on 1 side is
 greater than the other, trouble speaking or thinking, change in balance, or
 change in eyesight.

What are some other side effects of this drug?

All drugs may cause side effects. However, many people have no side effects or only have minor side effects. Call your doctor or get medical help if any of these side effects or any other side effects bother you or do not go away:

- · Headache.
- Stomach pain or diarrhea.
- Upset stomach or throwing up.
- Hair growth.
- Pimples (acne).
- · Dizziness.
- · Flushing.
- Signs of a common cold.
- · Joint pain.
- · Leg cramps.

These are not all of the side effects that may occur. If you have questions about side effects, call your doctor. Call your doctor for medical advice about side effects.

You may report side effects to your national health agency.

How is this drug best taken?

Use this drug as ordered by your doctor. Read all information given to you. Follow all instructions closely.

All oral products:

- Take with or without food but take the same way each time. Always take with food or always take on an empty stomach.
- If you are taking sirolimus, take it 4 hours after taking this drug.
- Keep taking this drug as you have been told by your doctor or other health care provider, even if you feel well.
- Take this drug at the same time of day.

Liquid (solution):

- Measure liquid doses carefully. Use the measuring device that comes with this drug.
- Do not rinse the syringe that comes with this drug before or after you take your dose. If you need to wash it, be sure it is completely dry before you use it again.

Gengraf® or Neoral®:

• Mix solution in glass with orange or apple juice at room temperature and drink it right away. Rinse glass with more liquid and drink.

Sandimmune®:

 Mix solution in glass with 1 cup of milk, chocolate milk, or orange juice at room temperature and drink it right away. Rinse glass with more juice or milk and drink.

Injection:

• It is given as an infusion into a vein over a period of time.

What do I do if I miss a dose?

All oral products:

- Take a missed dose as soon as you think about it.
- If it is close to the time for your next dose, skip the missed dose and go back to your normal time.
- Do not take 2 doses at the same time or extra doses.

Injection:

• Call your doctor to find out what to do.

How do I store and/or throw out this drug?

Capsules:

- Store in the original container at room temperature.
- Store in a dry place. Do not store in a bathroom.

Liquid (solution):

- Store at room temperature. Do not refrigerate or freeze.
- Store in original container.
- Throw away any unused portion 2 months after opening.
- Store in a dry place. Do not store in a bathroom.

Injection:

• If you need to store this drug at home, talk with your doctor, nurse, or pharmacist about how to store it.

All products:

- Keep all drugs in a safe place. Keep all drugs out of the reach of children and pets.
- Throw away unused or expired drugs. Do not flush down a toilet or pour down a drain unless you are told to do so. Check with your pharmacist if you have questions about the best way to throw out drugs. There may be drug take-back programs in your area.

General drug facts

- If your symptoms or health problems do not get better or if they become worse, call your doctor.
- Do not share your drugs with others and do not take anyone else's drugs.
- Some drugs may have another patient information leaflet. If you have any
 questions about this drug, please talk with your doctor, nurse, pharmacist, or
 other health care provider.
- If you think there has been an overdose, call your poison control center or get medical care right away. Be ready to tell or show what was taken, how much, and when it happened.

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Consumer Information Use and Disclaimer

This information should not be used to decide whether or not to take this medicine or any other medicine. Only the healthcare provider has the knowledge and training to decide which medicines are right for a specific patient. This information does not endorse any medicine as safe, effective, or approved for treating any patient or health condition. This is only a brief summary of general information about this medicine. It does NOT include all information about the possible uses, directions, warnings, precautions, interactions, adverse effects, or risks that may apply to this medicine. This information is not specific medical advice and does not replace information you receive from the healthcare provider. You must talk with the healthcare provider for complete information about the risks and benefits of using this medicine. The use of this information is governed by the Lexicomp End User License Agreement, available at

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