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(For additional information <u>see</u> "Mycophenolate mofetil (Cellcept) and mycophenolate sodium (Myfortic):

<u>Drug information</u>" and <u>see</u> "Mycophenolate mofetil (Cellcept) and mycophenolate sodium (Myfortic):

<u>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

CellCept; CellCept Intravenous; Myfortic

Brand Names: Canada

ACH-Mycophenolate; APO-Mycophenolate; APO-Mycophenolic Acid; CellCept; CellCept IV; CO Mycophenolate [DSC]; JAMP-Mycophenolate; MAR-Mycophenolic Acid; Myfortic; SANDOZ Mycophenolate Mofetil; TEVA-Mycophenolate; VAN-Mycophenolate [DSC]

Warning

- Use of this drug during pregnancy may cause birth defects or death of the
 unborn baby. If you are able to become pregnant, you must use birth control
 that you can trust to prevent pregnancy while taking this drug. Your doctor
 must talk with you about how to avoid getting pregnant while taking this drug.
 A pregnancy test will be done right before starting this drug and repeated 8 to
 10 days later to show that you are NOT pregnant. If you get pregnant or plan
 on getting pregnant while taking this drug, call your doctor right away.
- This drug may raise the chance of getting cancer like lymphoma or skin cancer.
 Call your doctor right away if you have a change in color or size of a mole, a skin lump or growth, a big weight loss, night sweats, or swollen glands.
- 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.
- 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.

What is this drug used for?

- It is used to keep the body from harming the organ after an organ transplant.
- 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?

- 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 Lesch-Nyhan or Kelley-Seegmiller syndrome or a rare inherited deficiency of hypoxanthine-guanine phosphoribosyl-transferase (HGPRT).
- If you are taking any of these drugs: Azathioprine, cholestyramine, colesevelam, colestipol, norfloxacin with metronidazole, or sevelamer.
- If you are taking another drug that has the same drug in it.
- If you are able to get pregnant and are not using 2 kinds of birth control.
- If you are breast-feeding or plan to breast-feed.
 This is not a list of all drugs or health problems that interact with this drug.
 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.
- Avoid driving and doing other tasks or actions that call for you to be alert until
 you see how this drug affects you.
- If you have high blood sugar (diabetes), you will need to watch your blood sugar closely.
- Have blood work checked as you have been told by the doctor. Talk with the doctor.
- You may bleed more easily. Be careful and avoid injury. Use a soft toothbrush and an electric razor.
- 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.
- 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.
- 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.
- Hepatitis B or C testing may be done. A hepatitis B or C infection may get worse while taking this drug.
- Bleeding, holes, and ulcers in the GI (gastrointestinal) tract have happened with this drug. Sometimes, people have had to go to the hospital. Talk with the

doctor.

- This drug may cause diarrhea. If you get diarrhea, talk with your doctor about ways to lower this effect. Do not stop taking this drug without talking with your doctor.
- If you have phenylketonuria (PKU), talk with your doctor. Some products have phenylalanine.
- If you are 65 or older, use this drug with care. You could have more side effects.
- If your sex partner may get pregnant, you may need to protect your partner from pregnancy during treatment and for some time after your last dose. Talk with your doctor to see if you need to use birth control after your last dose.
- Birth control pills and other hormone-based birth control may not work as well to prevent pregnancy. Use 2 kinds of birth control while taking this drug.
- Use 2 kinds of birth control during treatment and for 6 weeks after your last dose.
- If you get pregnant while taking this drug or within 6 weeks after your last dose, 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 sugar like confusion, feeling sleepy, more thirst, more hungry, passing urine more often, flushing, fast breathing, or breath that

smells like fruit.

- 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.
- Signs of high or low 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 skin infection like oozing, heat, swelling, redness, or pain.
- Chest pain or pressure.
- Fast, slow, or abnormal heartbeat.
- Any unexplained bruising or bleeding.
- Throwing up blood or throw up that looks like coffee grounds.
- Black, tarry, or bloody stools.
- A burning, numbness, or tingling feeling that is not normal.
- Muscle cramps.
- Swelling.
- Pale skin.
- White patches in mouth.
- Vaginal itching or discharge.
- Yellow skin or eyes.
- Some people have had lung problems with this drug. Sometimes, this has been deadly. Call your doctor right away if you have signs of lung problems like shortness of breath or other trouble breathing, cough that is new or worse, or fever.

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:

All products:

- Back pain.
- Constipation, diarrhea, stomach pain, upset stomach, throwing up, or feeling less hungry.
- · Headache.
- Gas.
- Feeling dizzy, tired, or weak.
- Shakiness.
- Trouble sleeping.
- · Joint pain.

Injection:

• Irritation where the shot is given.

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 on an empty stomach at least 1 hour before or 2 hours after meals unless your doctor has told you otherwise.
- 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.

• Take antacids that have aluminum or magnesium in them at least 2 hours after taking this drug.

All tablet products:

- Swallow whole. Do not chew, break, or crush.
- If you have trouble swallowing, talk with your doctor.

Capsules:

- Swallow whole. Do not chew, open, or crush.
- If you have trouble swallowing, talk with your doctor.
- If the capsule is opened or broken, do not touch the contents. If the contents are touched or they get in the eyes, wash hands or eyes right away.

<u>Liquid (suspension):</u>

- Shake well before use.
- Measure liquid doses carefully. Use the measuring device that comes with this drug.
- Do not mix with any other liquid drugs.
- If you get this drug on the skin, wash it off right away with soap and water.
- If this drug gets in the eyes, rinse with cool water.
- Those who have feeding tubes may use this drug. Use as you have been told. Flush the feeding tube after this drug is given.

Injection:

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

All products:

- 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.
- You may need to avoid donating blood while taking this drug and for some time after. Talk with your doctor.
- You may need to avoid donating sperm while taking this drug and for some

time after. If you have questions, talk with your doctor.

What do I do if I miss a dose?

Delayed-release tablets:

- 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.

All other oral products:

- Take a missed dose as soon as you think about it.
- If it is less than 2 hours until 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?

Liquid (suspension):

- Store at room temperature or in a refrigerator. Do not freeze.
- Throw away any unused part 60 days after this drug was mixed. Talk with your pharmacist if you are not sure when this is.

<u>All other oral products:</u>

• Store at room temperature protected from light. 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.

Last Reviewed Date

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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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