Memorial Sloan Kettering Cancer Center

PATIENT & CAREGIVER EDUCATION

Tacrolimus (Systemic

This information from UpToDate® Lexidrug™ explains what you need to know about this medication, including what it's used for, how to take it, its side effects, and when to call your healthcare provider.

Brand Names: US

Astagraf XL; Envarsus XR; Prograf

Brand Names: Canada

ACH-Tacrolimus; Advagraf; Envarsus PA; Prograf; SANDOZ Tacrolimus; SANDOZ Tacrolimus XR

Warning

All products:

- This drug may raise the chance of getting cancer like lymphoma or skin cancer. Talk with the doctor.
- Have your skin checked. Tell your doctor if you have any skin changes like a new wart, skin sore or reddish bump that bleeds or does not heal, or a change in the color or size of a mole.
- Call your doctor right away if you have a swollen gland, night sweats, shortness of breath, or weight loss without trying.
- This drug may raise the chance of very bad and sometimes deadly infections. 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.

Extended-release capsules:

- In one study of patients who used this drug after a liver transplant, a larger number of deaths happened in females. This drug is not for use after a liver transplant.

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 a long QT on ECG.
- If you are taking any of these drugs: Cyclosporine or sirolimus.
- If you or your sex partner are pregnant. This drug may cause harm to the unborn baby.
- If you or your sex partner may get pregnant. Talk with the doctor about birth control methods before you start this drug. If you or your partner get pregnant while you are taking this drug, call your doctor right away.
- 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.
- Check your drug when you get a new prescription to make sure you have the right drug. Call your doctor right away if you think you were given the wrong drug or if you are not sure what your drug should look like.
- You may have more chance of getting an infection. Wash hands often. Stay away from people with infections, colds, or flu.
- Have your blood work and other lab tests checked as you have been told by

your doctor.

- Many other drugs affect how much of this drug is in your body. This may raise the chance of organ rejection or raise the chance of side effects. If you take other drugs, check with your doctor to see if you need to have your blood work checked more closely while taking them with this drug.
- If you are taking a salt substitute that has potassium in it, a potassium-sparing diuretic, or a potassium product, talk with your doctor.
- Avoid grapefruit and grapefruit juice.
- High blood pressure has happened with this drug. Have your blood pressure checked as you have been told by your doctor.
- High blood sugar has happened with this drug. This includes diabetes that is new or worse.
- Check your blood sugar as you have been told by your doctor.
- Tell your doctor if you have signs of high blood sugar like confusion, feeling sleepy, unusual thirst or hunger, passing urine more often, flushing, fast breathing, or breath that smells like fruit.
- If you are not up to date with all of your vaccines, talk with your doctor. You may need to have some vaccines before treatment with this drug.
- 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 drinking alcohol with some products. Talk with your doctor or pharmacist to see if you need to avoid drinking alcohol with this drug.
- 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.
- This drug may affect fertility. Fertility problems may lead to not being able to get pregnant or father a child. If you plan to get pregnant or father a child, talk with your doctor before taking this drug.

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 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, cramps, or spasms; weakness; shakiness; change in balance; an abnormal heartbeat; seizures; loss of appetite; or severe upset stomach or throwing up.
- Signs of high blood pressure like very bad headache or dizziness, passing out, or change in eyesight.
- Signs of too much acid in the blood (acidosis) like confusion; fast breathing; fast heartbeat; a heartbeat that does not feel normal; very bad stomach pain, upset stomach, or throwing up; feeling very sleepy; shortness of breath; or feeling very tired or weak.
- Warm, red, or painful skin or sores on the body.
- Chest pain or pressure.
- Shortness of breath, a big weight gain, or swelling in the arms or legs.
- Shakiness.
- Trouble moving around.
- Any unexplained bruising or bleeding.
- A burning, numbness, or tingling feeling that is not normal.
- Pale skin.

- A severe 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, 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.
- 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.
- This drug may cause a type of abnormal heartbeat (prolonged QT interval). If this happens, the chance of other unsafe and sometimes deadly abnormal heartbeats may be raised.
- Severe and sometimes deadly holes in the GI (gastrointestinal) tract have happened with this drug. Tell your doctor if you have severe stomach pain; black, tarry, or bloody stools; throwing up blood; or vomit that looks like coffee grounds.
- Severe blood problems like thrombotic thrombocytopenic purpura/hemolytic uremic syndrome (TTP/HUS) have happened with some forms of this drug. Call your doctor right away if you feel confused, very tired or weak or if you have any bruising; bleeding; dark urine; yellow skin or eyes; pale skin; change in the amount of urine passed; change in eyesight; change in strength on 1 side; trouble speaking or thinking; change in balance; 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:

- Feeling dizzy, tired, or weak.
- Headache.
- Constipation, diarrhea, stomach pain, upset stomach, throwing up, or

decreased appetite.

- Heartburn.
- Trouble sleeping.
- Back pain.
- Joint pain.
- Nose or throat irritation.

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.

You may report side effects to the FDA at 1-800-332-1088. You may also report side effects at https://www.fda.gov/medwatch.

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:

- 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.

Immediate-release capsules and granules:

- Take with or without food but take the same way each time. Always take with food or always take on an empty stomach.

Immediate-release capsules:

- Swallow whole. Do not chew, open, or crush.

Granules:

- You will need to take special care when handling this drug. Check with the doctor or pharmacist to see how to handle this drug.
- Avoid breathing in powder.
- 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.
- Be sure you know what the dose of this drug is. Be sure you know which types of packets to use to make up the dose. Talk to the doctor if you are not sure.
- Use glass or metal materials to prepare the dose. Do not use plastic materials.
- Empty packet contents into a glass. Add 1 to 2 tablespoons (15 to 30 mL) of room temperature water to the glass and mix. The granules will not dissolve all the way. After you take the dose, rinse the glass with the same amount of water and drink.
- After mixing, take your dose right away. Do not store for future use.
- Do not sprinkle this drug on food.
- If needed for a dose, you can use the oral syringe that comes with this drug.
- If giving this drug to your child and your child's weight changes, talk with the doctor. The dose of this drug may need to be changed.

All extended-release products:

- Take in the morning on an empty stomach. Take at least 1 hour before or at least 2 hours after breakfast.
- Swallow whole with a drink of water.
- If you have trouble swallowing, talk with your doctor.

Extended-release capsules:

- Do not chew, break, or crush.

Extended-release tablets:

- Do not chew, break, crush, or dissolve.

Infusion:

- It is given as an infusion into a vein over a period of time.
- You will be watched closely while you receive this drug and for some time after your dose. Talk with your doctor.

What do I do if I miss a dose?

Immediate-release capsules and granules:

- 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.

Extended-release capsules:

- Take a missed dose as soon as you think about it.
- If it has been 14 hours or more since the missed dose, skip the missed dose and go back to your normal time.
- Do not take 2 doses at the same time or extra doses.

Extended-release tablets:

- Take a missed dose as soon as you think about it.
- If it has been more than 15 hours since the missed dose, skip the missed dose and go back to your normal time.
- Do not take 2 doses at the same time or extra doses.

Infusion:

- Call your doctor to find out what to do.

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

All oral products:

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

Infusion:

- 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.
- Some drugs may have another patient information leaflet. Check with your pharmacist. 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.

Consumer Information Use and Disclaimer

This generalized information is a limited summary of diagnosis, treatment, and/or medication information. It is not meant to be comprehensive and should be used as a tool to help the user understand and/or assess potential diagnostic and treatment options. It does NOT include all information about conditions, treatments, medications, side effects, or risks that may apply to a specific patient. It is not intended to be medical advice or a substitute for the medical advice, diagnosis, or treatment of a health care provider based on the health care provider's examination and assessment of a patient's specific and unique circumstances. Patients must speak with a health care provider for complete information about their health, medical questions, and treatment options, including any risks or benefits regarding use of medications. This information does not endorse any treatments or medications as safe, effective, or approved for treating a specific patient. UpToDate, Inc. and its affiliates disclaim any warranty or liability relating to this information or the use thereof. The use of this information is governed by the Terms of Use, available at https://www.wolterskluwer.com/en/know/clinical-effectiveness-terms.

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If you have questions or concerns, contact your healthcare provider. A member of your care team will answer Monday through Friday from 9 a.m. to 5 p.m. Outside those hours, you can leave a message or talk with another MSK provider. There is always a doctor or nurse on call. If you're not sure how to reach your healthcare provider, call 212-639-2000.

For more resources, visit www.mskcc.org/pe to search our virtual library.

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