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 child's skin checked. Tell your child's doctor if your child has 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 child's doctor right away if your child has 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 child's doctor right away if your child has 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 your child for other reasons. Talk with the doctor.

What do I need to tell the doctor BEFORE my child takes this drug?

- If your child is allergic to this drug; any part of this drug; or any other drugs, foods, or substances. Tell the doctor about the allergy and what signs your child had.
- If your child has a long QT on ECG.
- If your child is taking any of these drugs: Cyclosporine or sirolimus.

This is not a list of all drugs or health problems that interact with this drug.

Tell the doctor and pharmacist about all of your child's drugs (prescription or OTC, natural products, vitamins) and health problems. You must check to make sure that it is safe to give this drug with all of your child's other drugs and health problems. Do not start, stop, or change the dose of any drug your child takes without checking with the doctor.

What are some things I need to know or do while my child takes this drug?

- Tell all of your child's health care providers that your child is taking this drug. This includes your child's doctors, nurses, pharmacists, and dentists.
- Check your child's drug when you get a new prescription

to make sure you have the right drug. Call the doctor right away if you think you were given the wrong drug or if you are not sure what your child's drug should look like.

- Your child may have more chance of getting infections. Have your child wash hands often. Avoid crowds and people with infections, colds, or flu.
- Have your child's blood work and other lab tests checked as you have been told by the doctor.
- Many other drugs affect how much of this drug is in your child's body. This may raise the chance of organ rejection or raise the chance of side effects. If your child takes other drugs, check with the doctor to see if your child needs to have blood work checked more closely while taking them with this drug.
- High blood pressure has happened with this drug. Have your child's blood pressure checked as you have been told by the doctor.
- High blood sugar has happened with this drug. This includes diabetes that is new or worse.
- Check your child's blood sugar as you have been told by the doctor.
- Avoid giving your child grapefruit and grapefruit juice.
- If your child is taking a salt substitute that has potassium

in it, a potassium-sparing diuretic, or a potassium product, talk with your child's doctor.

- If your child is not up to date with vaccines, talk with your child's doctor. Your child may need to have some vaccines before treatment with this drug.
- Talk with the doctor before your child gets any vaccines. Use of some vaccines with this drug may either raise the chance of very bad infection or make the vaccine not work as well.
- Alcohol may interact with this drug. Be sure your child does not drink alcohol.
- There is a chance of skin cancer. Have your child avoid lots of sun, sunlamps, and tanning beds. Use sunscreen and dress your child in clothing and eyewear that protects your child 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 have questions, talk with the doctor before your child takes this drug.

If your child is or may be sexually active:

- This drug may cause harm to the unborn baby if taken during pregnancy. All people who will be taking this drug must talk with the doctor about birth control methods.

- If your child is pregnant or gets pregnant while taking this drug, call the doctor right away.
- If your child's sex partner is pregnant or gets pregnant at any time while your child is being treated, talk with the doctor.

If your child is breast-feeding a baby:

- Tell the doctor if your child is breast-feeding a baby. You will need to talk about any risks to the baby.

What are some side effects that I need to call my child's 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 child's doctor or get medical help right away if your child has 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 high blood sugar like confusion, feeling sleepy, unusual thirst or hunger, passing urine more often, flushing, fast breathing, or breath that smells like fruit.
- 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) may happen with this drug. It may cause disability or death. Tell the doctor right away if your child has signs like confusion, memory problems, depression, change in the way your child acts, 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 the doctor right away if your child has 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 the doctor if your child has 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 this drug. Call the doctor right away if your child feels confused, very tired or weak or has 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 child's doctor or get medical help if any of these side effects or any other side effects bother your child 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 child's doctor. Call your child's doctor for medical advice about side effects.

You may report side effects to your national health agency.

How is this drug best given?

Give this drug as ordered by your child's doctor. Read all information given to you. Follow all instructions closely.

All oral products:

- Keep giving this drug to your child as you have been told by your child's doctor or other health care provider, even if your child feels well.
- Give this drug at the same time of day.

Immediate-release capsules and granules:

- Give this drug with or without food but give it the same way each time. Always give with food or always give on an empty stomach.

Immediate-release capsules:

- Have your child swallow whole. Do not let your child 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 your child takes the dose, rinse the glass with the same amount of water and have your child drink.
- After mixing, give the 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:

- Give in the morning on an empty stomach. Give at least 1 hour before or at least 2 hours after breakfast.
- If your child has trouble swallowing, talk with the doctor.

Extended-release capsules:

- Do not let your child chew, break, or crush.

Extended-release tablets:

- Do not let your child chew, break, crush, or dissolve.

Infusion:

- It is given as an infusion into a vein over a period of time.
- Your child will be watched closely while getting this drug and for some time after the dose. Talk with your child's doctor.

What do I do if my child misses a dose?

Immediate-release capsules and granules:

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

Extended-release capsules:

- Give 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 child's normal time.
- Do not give 2 doses at the same time or extra doses.

Extended-release tablets:

- Give 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 child's normal time.
- Do not give 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 child's 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 child's symptoms or health problems do not get better or if they become worse, call your child's doctor.
- Do not share your child's drug with others and do not give anyone else's drug to your child.
- Some drugs may have another patient information

leaflet. If you have any questions about this drug, please talk with your child's 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

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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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