

MEDICATION GUIDE
ASTAGRAF XL® [as' tah graf ex el']
(tacrolimus)
extended-release capsules

Read this Medication Guide before you start taking ASTAGRAF XL and each time you get a refill. There may be new information. This information does not take the place of talking with your healthcare provider about your medical condition or your treatment. If you have any questions about ASTAGRAF XL, ask your healthcare provider or pharmacist.

What is the most important information I should know about ASTAGRAF XL?

ASTAGRAF XL can cause serious side effects, including:

- **Increased risk of cancer.** People who take ASTAGRAF XL have an increased risk of getting some kinds of cancer, including skin and lymph gland cancer (lymphoma).
- **Increased risk of infection.** ASTAGRAF XL is a medicine that affects your immune system. ASTAGRAF XL can lower the ability of your immune system to fight infections. Serious infections can happen in people receiving ASTAGRAF XL that can cause death. **Call your healthcare provider right away if you have symptoms of an infection such as:**
 - fever
 - cough or flu-like symptoms
 - warm, red, or painful areas on your skin
 - sweats or chills
 - muscle aches
- **Increased risk of death in females who have had a liver transplant.** You should not take ASTAGRAF XL if you have had a liver transplant without talking to your healthcare provider.

What is ASTAGRAF XL?

- ASTAGRAF XL is a prescription medicine used with other medicines to help prevent organ rejection in people who have had a kidney transplant.
- ASTAGRAF XL is an extended-release capsule and is not the same as tacrolimus immediate-release capsules, tacrolimus for oral suspension or tacrolimus extended-release tablets. Your healthcare provider should decide what medicine is right for you.

Who should not take ASTAGRAF XL?

- **Do not** take ASTAGRAF XL if you are allergic to tacrolimus or any of the ingredients in ASTAGRAF XL. See the end of this leaflet for a complete list of ingredients in ASTAGRAF XL.

Before you take ASTAGRAF XL tell your healthcare provider if you:

- plan to receive any live vaccines. Ask your healthcare provider if you are not sure if your vaccine is a live vaccine.
- have or have had liver, kidney, or heart problems **or** any other medical conditions.
- are pregnant or plan to become pregnant. ASTAGRAF XL may harm your unborn baby.
 - If you are able to become pregnant, you should use effective birth control before and during treatment with ASTAGRAF XL. Talk to your healthcare provider before starting treatment with ASTAGRAF XL about birth control methods that may be right for you.
 - Males who have female partners that are able to become pregnant should also use effective birth control before and during treatment with ASTAGRAF XL. Talk to your healthcare provider before starting treatment with ASTAGRAF XL about birth control methods that may be right for you.
 - There is a pregnancy registry for females who become pregnant and males who have fathered a pregnancy during treatment with ASTAGRAF XL. The purpose of this registry is to collect information about your health and of your baby. To enroll in this voluntary registry, call 1-877-955-6877 or go to <https://www.transplantpregnancyregistry.org/>.
- are breastfeeding or plan to breastfeed. ASTAGRAF XL passes into your breast milk. You and your healthcare provider should decide if you will breastfeed while taking ASTAGRAF XL.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, natural, herbal or nutritional supplements. ASTAGRAF XL may affect the way other medicines work, and other medicines may affect how ASTAGRAF XL works.

How should I take ASTAGRAF XL?

- Take ASTAGRAF XL exactly as your healthcare provider tells you to take it.
- Your healthcare provider may change your dose if needed. **Do not** stop taking or change your dose of ASTAGRAF XL without talking to your healthcare provider.
- Take ASTAGRAF XL capsules whole. Do not break, crush, chew, or dissolve ASTAGRAF XL capsules before swallowing. If you cannot swallow ASTAGRAF XL capsules whole, tell your healthcare provider.
- Take ASTAGRAF XL at the same time each morning, preferably on an empty stomach at least 1 hour before, or at least 2 hours after, you have eaten a meal.
- If you miss your dose of ASTAGRAF XL, it should be taken as soon as possible, but no longer than 14 hours after your regularly scheduled time. If it is longer than 14 hours, the missed dose should be skipped and the next dose should be taken the following morning at your regularly scheduled time. **Do not** take 2 doses at the same time.
- If you take too much ASTAGRAF XL, call your healthcare provider or go to the nearest hospital emergency room right away.

What should I avoid while taking ASTAGRAF XL?

- Live vaccines such as flu vaccine through your nose, measles, mumps, rubella, polio by mouth, BCG (TB vaccine), yellow fever, chicken pox (varicella) or typhoid.
- Exposure to sunlight and UV light such as tanning machines. Wear protective clothing and use a sunscreen.
- You should not eat grapefruit or drink grapefruit juice while taking ASTAGRAF XL.
- You should not drink alcohol when taking ASTAGRAF XL.

What are the possible side effects of ASTAGRAF XL?

ASTAGRAF XL may cause serious side effects, including:

- **See “What is the most important information I should know about ASTAGRAF XL?”**
- **Problems from medication errors such as graft rejection and other serious reactions.** People who take ASTAGRAF XL have sometimes been given the wrong medicine because some medicines have the same ingredient (tacrolimus) as ASTAGRAF XL. Serious reactions have happened including graft rejection. **Check your ASTAGRAF XL when you get a new prescription to make sure you have received the right medicine.**
 - Call your healthcare provider right away if you think you were given the wrong medicine
 - Ask your healthcare provider or pharmacist if you are not sure what ASTAGRAF XL should look like.
- **high blood sugar (diabetes).** Your healthcare provider may do certain tests to check for diabetes while you take ASTAGRAF XL. Call your healthcare provider right away if you have:
 - frequent urination
 - increased thirst or hunger
 - blurred vision
 - confusion
 - drowsiness
 - loss of appetite
 - fruity smell on your breath
 - nausea, vomiting, or stomach pain
- **kidney problems.** Kidney problems are serious and common side effects of ASTAGRAF XL. Your healthcare provider may do certain tests to check your kidney function while you take ASTAGRAF XL.
- **nervous system problems.** Nervous system problems are a serious and common side effect of ASTAGRAF XL. Call your healthcare provider or go to the nearest hospital emergency room right away if you get any of these symptoms while taking ASTAGRAF XL. These could be signs of serious nervous system problems:
 - confusion
 - changes in alertness
 - muscle tremors
 - numbness and tingling
 - headache
 - seizures
 - vision changes
- **high levels of potassium in your blood.** Your healthcare provider may do certain tests to check your potassium level while you take ASTAGRAF XL.
- **high blood pressure.** High blood pressure is a serious and common side effect of ASTAGRAF XL. Your healthcare provider will monitor your blood pressure while you take ASTAGRAF XL and may ask you to check your blood pressure at home.
- **changes in the electrical activity of your heart (QT prolongation).**
- **severe low blood cell count (anemia).**

The most common side effects of ASTAGRAF XL are diarrhea, constipation, nausea, swelling of the hands, ankles, or legs, and tremors (shaking of the body).

These are not all the possible side effects of ASTAGRAF XL. For more information, ask your healthcare provider or pharmacist.
Call your healthcare provider for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store ASTAGRAF XL?

- Store ASTAGRAF XL at room temperature between 68°F to 77°F (20°C to 25°C).
- Safely throw away medicine that is out of date or no longer needed.
- **Keep ASTAGRAF XL and all medicines out of reach of children.**

General information about the safe and effective use of ASTAGRAF XL.

- Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use ASTAGRAF XL for a condition for which it was not prescribed. Do not give ASTAGRAF XL to other people, even if they have the same symptoms that you have. It may harm them.
- This Medication Guide summarizes the most important information about ASTAGRAF XL. If you would like more information, talk to your healthcare provider. You can ask your pharmacist or healthcare provider for information about ASTAGRAF XL that is written for health professionals.

What are the ingredients in ASTAGRAF XL?

Active ingredient: tacrolimus.

Inactive ingredients:

- **The capsule contains:** ethylcellulose NF, hypromellose USP, magnesium stearate NF, and lactose monohydrate NF
- **The capsule shell contains:** gelatin NF, titanium dioxide USP, ferric oxide NF, and sodium lauryl sulfate

Manufactured by: **Astellas Ireland Co., Limited**, Killorglin, County Kerry, Ireland

Marketed by: **Astellas Pharma US, Inc.**, Northbrook, IL 60062

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This Medication Guide has been approved by the U.S. Food and Drug Administration

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