

MEDICATION GUIDE

ASTAGRAF XL™ [as' tah graf ex el']

(tacrolimus)

extended-release capsules

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

ASTAGRAF XL can cause serious side effects, including:

1. **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).
2. **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 doctor right away if you have symptoms of an infection such as:**
 - fever
 - sweats or chills
 - cough or flu-like symptoms
 - muscle aches
 - warm, red, or painful areas on your skin
3. **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 doctor.

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. Your doctor should decide what medicine is right for you.

ASTAGRAF XL is not for use with medicines called cyclosporine (e.g., Neoral[®], Sandimmune[®], and Gengraf[®]).

It is not known if ASTAGRAF XL is safe and effective when used with sirolimus (Rapamune[®]) in people who have had kidney transplants.

It is not known if ASTAGRAF XL is safe and effective in children under 16 years of age who have had kidney transplants.

What should I tell my doctor before taking ASTAGRAF XL?

Before you take ASTAGRAF XL, tell your doctor if you:

- plan to receive any live vaccines. Ask your doctor if you are not sure if your vaccine is a live vaccine.
- have or have had liver, kidney or heart problems.
- have any other medical conditions.
- are pregnant or plan to become pregnant. ASTAGRAF XL may harm your unborn baby. Talk to your doctor if you are pregnant or plan to become pregnant.
- are breastfeeding or plan to breastfeed. ASTAGRAF XL can pass into your breast milk. You and your doctor should decide if you will take ASTAGRAF XL or breastfeed. You should not do both.

Tell your doctor about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

ASTAGRAF XL may affect the way other medicines work, and other medicines may affect how ASTAGRAF XL works.

Know the medicines you take. Keep a list of them and show it to your doctor and pharmacist when you get a new medicine. Tell your doctor or pharmacist if there are any changes to the list of medicines that you take.

How should I take ASTAGRAF XL?

- Take ASTAGRAF XL exactly as your doctor tells you to take it.
- Your doctor will tell you how much ASTAGRAF XL to take and when to take it.
- Your doctor may change your dose of ASTAGRAF XL if needed. **Do not** stop taking or change your dose of ASTAGRAF XL without talking to your doctor.
- 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 doctor.
- 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.
- Taking ASTAGRAF XL at the same time each day helps to keep enough medicine in your body to give your transplanted organ the around-the-clock medicine it needs.
- 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 doctor or go to the nearest hospital emergency room right away.

What should I avoid while taking ASTAGRAF XL?

- While you take ASTAGRAF XL you should not receive any live vaccines such as:
 - flu vaccine through your nose
 - measles
 - mumps
 - rubella
 - polio by mouth
 - BCG (TB vaccine)
 - yellow fever
 - chicken pox (varicella)
 - typhoid
- Avoid 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 an alcoholic beverage when taking ASTAGRAF XL. It can increase your chances of getting serious side effects.

What are the possible side effects of ASTAGRAF XL?

ASTAGRAF XL may cause serious side effects, including:

- **See “What the most important information I should know about ASTAGRAF XL?”**
- **medication errors.** People who take ASTAGRAF XL have sometimes been given the wrong medicine because some medicines have the same ingredient (medicine) as ASTAGRAF XL. **You should check your ASTAGRAF XL when you get a new prescription to make sure you have received the right medicine.**
 - Call your doctor right away if you think you were given the wrong medicine.
 - Ask your doctor or pharmacist if you are not sure what ASTAGRAF XL should look like.
- **high blood sugar (diabetes).** Your doctor may do certain tests to check for diabetes while you take ASTAGRAF XL. Call your doctor 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.** Your doctor may do certain tests to check your kidney function while you take ASTAGRAF XL.

- **nervous system problems.** Call your doctor right away if you get any of these symptoms while taking ASTAGRAF XL. These could be signs of a serious nervous system problem:
 - confusion
 - coma
 - muscle tremors
 - numbness and tingling
 - headache
 - seizures
 - vision changes
- **high levels of potassium in your blood.** Your doctor may do certain tests to check your potassium level while you take ASTAGRAF XL.
- **high blood pressure.** Your doctor will monitor your blood pressure while you take ASTAGRAF XL.
- **Changes in the electrical activity of your heart (QT prolongation).**

The most common side effects of ASTAGRAF XL in people receiving kidney transplant are:

- diarrhea
- constipation
- nausea
- swelling of the hands, ankles, or legs
- tremors (shaking of the body)
- low red blood cell count (anemia)

Tell your doctor if you have any side effect that bothers you or that does not go away.

These are not all the possible side effects of ASTAGRAF XL. For more information, ask your doctor or pharmacist.

Call your doctor 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 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 with your doctor. You can ask your pharmacist or doctor for information about ASTAGRAF XL that is written for health professionals.

For more information, go to www.ASTAGRAFXL.com or call 1-800-727-7003.

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

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

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