

PATIENT INFORMATION
Hecoria™ (tacrolimus) Capsules

Read this Patient Information before you start taking Hecoria (tacrolimus) capsules and each time you get a refill. There may be new information. This information does not take the place of talking with your doctor about your medical condition or your treatment.

What is the most important information I should know about Hecoria (tacrolimus) capsules?

Hecoria (tacrolimus) capsules can cause serious side effects, including:

- 1. Increased risk of cancer.** People who take Hecoria have an increased risk of getting some kinds of cancer, including skin and lymph gland cancer (lymphoma).
- 2. Increased risk of infection.** Hecoria is a medicine that affects your immune system. Hecoria can lower the ability of your immune system to fight infections. Serious infections can happen in people receiving Hecoria 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

What are Hecoria (tacrolimus) capsules?

Hecoria is a prescription medicine used with other medicines to help prevent organ rejection in people who have had a kidney or liver transplant and

Hecoria is not for use with medicines called cyclosporines (Gengraf[®], Neoral[®], and Sandimmune[®]).

Hecoria is not for use with a medicine called sirolimus (Rapamune[®]) in people who have had a liver transplant.

It is not known if Hecoria is safe and effective when used with sirolimus in people who have had kidney transplants.

It is not known if Hecoria is safe and effective in children who have had a kidney transplant.

Who Should Not Take Hecoria (tacrolimus) capsules?

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

What should I tell my doctor before taking Hecoria (tacrolimus) capsules?

Before you take Hecoria, tell your doctor if you:

- plan to receive any live vaccines
- have or have had liver, kidney or heart problems
- are pregnant or plan to become pregnant. Hecoria may harm your unborn baby. Talk to your doctor if you are pregnant or plan to become pregnant.
- Are breastfeeding or plan to breastfeed. Hecoria can pass into your breast milk. You and your doctor should decide if you will take Hecoria or breastfeed. You should not do both.

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

Especially tell your doctor if you take:

- cyclosporine (Gengraf[®], Neoral[®], and Sandimmune[®])
- sirolimus (Rapamune[®])
- nelfinavir (Viracept[®])

Ask your doctor or pharmacist if you are not sure if you take any of the medicines listed above.

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

Know the medicines you take. Keep a list of your medicines and show it to your doctor and pharmacist when you get a new medicine.

How Should I Take Hecoria (tacrolimus) capsules?

- Take Hecoria exactly as your doctor tells you to take it.
- Your doctor will tell you how many Hecoria capsules to take and when to take them.
- Your doctor may change your Hecoria dose if needed. **Do not** stop taking or change your dose of Hecoria without talking to your doctor.
- Take Hecoria with or without food.
- Take Hecoria the same way everyday. For example, if you choose to take Hecoria with food, you should always take Hecoria with food.
- Take Hecoria at the same time each day, 12 hours apart. For example, if you take your first dose at 7:00 a.m. you should take your second dose at 7:00 p.m.
 - Taking Hecoria 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.
- **Do not** eat grapefruit or drink grapefruit juice while taking Hecoria.
- If you take too much Hecoria, call your doctor or go to the nearest hospital emergency room right away.

What should I avoid while taking Hecoria (tacrolimus) capsules?

- While you take Hecoria 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.

What are the possible side effects of Hecoria (tacrolimus) capsules?

Hecoria may cause serious side effects, including:

- See “**What is the most important information I should know about Hecoria?**”
- **high blood sugar (diabetes).** Your doctor may do certain tests to check for diabetes while you take Hecoria. 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 Hecoria.
- **nervous system problems.** Call your doctor right away if you get any of these symptoms while taking Hecoria. 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 Hecoria.
- **high blood pressure.** Your doctor will monitor your blood pressure while you take Hecoria.
- **heart problems (myocardial hypertrophy).** Tell your doctor right away if you get any of these symptoms of heart problems while taking Hecoria:
 - shortness of breath
 - chest pain
 - feel lightheaded

- feel faint

The most common side effects of Hecoria (tacrolimus) capsules in people receiving kidney transplant are:

- infection
- tremors (shaking of the body)
- high blood pressure
- kidney problems
- constipation
- diarrhea
- headache
- stomach pain
- trouble sleeping
- nausea
- low levels of phosphate in your blood
- swelling of the hands, ankles, or legs
- weakness
- pain
- high levels of fat in your blood
- high levels of potassium in your blood
- low red blood cell count (anemia)

The most common side effects of Hecoria (tacrolimus) capsules in people receiving liver transplants are:

- shaking of the body tremors
- headache
- diarrhea
- high blood pressure
- nausea
- kidney problems
- stomach pain
- trouble sleeping
- numbness or tingling in your hands or feet
- anemia
- pain
- fever
- weakness
- high levels of potassium in the blood
- low levels of magnesium in the blood

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 Hecoria. 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 Hecoria (tacrolimus) capsules?

- Store Hecoria at 20° to 25°C (68° to 77° F).
- Safely throw away medicine that is out of date or no longer needed.

Keep Hecoria and all medicines out of reach of children.

General information about the safe and effective use of Hecoria (tacrolimus) capsules

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use Hecoria for a condition for which it was not prescribed. Do not give Hecoria to other people, even if they have the same symptoms that you have. It may harm them.

How Does Hecoria (tacrolimus) capsules Protect My New Organ?

The body's immune system protects the body against anything that it does not recognize as part of the body. For example, when the immune system detects a virus or bacteria it tries to get rid of it to prevent infection. When a person has a liver or kidney transplant, the immune system does not recognize the new organ as a part of the body and tries to get rid of it, too. This is called "rejection". Hecoria protects your new organ by slowing down the body's immune system.

This Patient Information leaflet summarizes the most important information about Hecoria. If you would like more information, talk with your doctor. You can ask your pharmacist or doctor for information about Hecoria that is written for health professionals.

For more information contact Novartis Pharmaceuticals Corporation at 1-888-669-6682.

What are the ingredients in Hecoria (tacrolimus) capsules?

Active ingredient: tacrolimus

Inactive ingredients: croscarmellose sodium, hypromellose, lactose monohydrate, and magnesium stearate.

The Hecoria capsule shell for 0.5 mg strength consists of gelatin, titanium dioxide and yellow iron oxide.

The Hecoria capsule shell for 1 mg strength consists of black iron oxide, gelatin, red iron oxide, titanium dioxide, and yellow iron oxide.

The Hecoria capsule shell for 5 mg strength consists of red iron oxide, gelatin, and titanium dioxide.

Hecoria capsules 0.5 mg, 1 mg and 5 mg are printed with edible black ink. The black ink is comprised of ammonia, black iron oxide, butyl alcohol, potassium hydroxide, propylene glycol, and shellac.

This Patient Information has been approved by the U.S. Food and Drug Administration.

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