

Medication Guide
LUPKYNIS™ (loop kye' nis)
(voclosporin) capsules, for oral use

Read this Medication Guide before you start taking LUPKYNIS 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 LUPKYNIS, ask your healthcare provider or pharmacist.

What is the most important information I should know about LUPKYNIS?

LUPKYNIS can cause serious side effects, including:

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

See “**What are the possible side effects of LUPKYNIS?**” for more information about side effects.

What is LUPKYNIS?

- LUPKYNIS is a prescription medicine used with other medicines to treat adults with active lupus nephritis.
- LUPKYNIS should not be taken with a medicine called cyclophosphamide. Talk with your healthcare provider if you are not sure if you take this medicine.

Do not take LUPKYNIS:

- with medicines known as strong CYP3A4 inhibitors such as ketoconazole, itraconazole, and clarithromycin.
- if you are allergic to voclosporin or any of the ingredients in LUPKYNIS. See the end of this Medication Guide for a complete list of ingredients in LUPKYNIS.

Before you take LUPKYNIS, tell your healthcare provider about all your medical conditions, including if you:

- plan to receive any vaccines. You should not receive any live vaccines during treatment with LUPKYNIS. Ask your healthcare provider if you are not sure if your vaccine is a live vaccine. Other vaccines may not work as well during treatment with LUPKYNIS.
- have or have had liver, kidney, or heart problems.
- have high blood pressure.
- are pregnant or plan to become pregnant when taking LUPKYNIS. LUPKYNIS may harm your unborn baby.
 - When taking LUPKYNIS in combination with mycophenolate mofetil, you should also read the Medication Guide for mycophenolate mofetil for important pregnancy information.
- are breastfeeding or plan to breastfeed. You and your healthcare provider should decide if you will take LUPKYNIS or breastfeed. You should not do both. After you stop your treatment with LUPKYNIS, do not start breastfeeding again until 7 days after your last dose of LUPKYNIS.

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

How should I take LUPKYNIS?

- Take LUPKYNIS 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 LUPKYNIS without talking to your healthcare provider.
- Swallow LUPKYNIS capsules whole. **Do not** break, crush, chew or dissolve LUPKYNIS capsules before swallowing. If you cannot swallow LUPKYNIS capsules whole, tell your healthcare provider.
- Take LUPKYNIS on an empty stomach, either 1 hour before or 2 hours after a meal and as close to 12 hours between doses as possible. **Do not** take your doses of LUPKYNIS less than 8 hours apart. If a dose is missed, take it as soon as possible within 4 hours after missing the dose. If more than 4 hours has passed, skip the missed dose and take the next dose at the regular time. **Do not** take 2 doses at the same time.
- If you take too much LUPKYNIS, call your healthcare provider or go to the nearest hospital emergency room right away.
- Talk with your healthcare provider if you have been taking LUPKYNIS for close to one year. It is not known if taking LUPKYNIS is safe or effective beyond a year.

What should I avoid while taking LUPKYNIS?

- 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 LUPKYNIS.

What are the possible side effects of LUPKYNIS?

LUPKYNIS may cause serious side effects, including:

- See “**What is the most important information I should know about LUPKYNIS?**”
- **kidney problems.** Kidney problems are common side effects of LUPKYNIS and may be serious. Your healthcare provider may do certain tests to check your kidney function while you take LUPKYNIS.
- **high blood pressure.** High blood pressure is a common side effect of LUPKYNIS and may be serious. Your healthcare provider will monitor your blood pressure while you take LUPKYNIS and may ask you to check your blood pressure at home.
- **nervous system problems.** Nervous system problems are a common side effect of LUPKYNIS and may be serious. Call your healthcare provider or go to the nearest hospital emergency room right away if you get any of these symptoms while taking LUPKYNIS. These could be signs of serious nervous system problems:
 - confusion
 - numbness and tingling
 - seizures
 - changes in alertness
 - headache
 - vision changes
 - muscle tremors
- **high levels of potassium in your blood.** Your healthcare provider may do certain tests to check your potassium levels while you take LUPKYNIS.
- **a serious heart rhythm problem (QT prolongation).**
- **severe low red blood cell count (anemia).**

The most common side effects of LUPKYNIS are:

- diarrhea
- urinary tract infection
- heartburn
- headache
- stomach pain
- loss of hair (alopecia)
- cough

These are not all the possible side effects of LUPKYNIS.

Call your healthcare provider for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

You may also report side effects to www.fda.gov/medwatch.

How should I store LUPKYNIS?

- Store LUPKYNIS at room temperature between 68°F to 77°F (20°C to 25°C).
- Do not put LUPKYNIS in another container. **Keep capsules in their original package until you are ready to take them.**
- **Keep LUPKYNIS and all medicines out of the reach of children.**

General information about the safe and effective use of LUPKYNIS

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use LUPKYNIS for a condition for which it was not prescribed. Do not give LUPKYNIS to other people, even if they have the same symptoms that you have. It may harm them. You can ask your pharmacist or healthcare provider for information about LUPKYNIS that is written for healthcare professionals.

What are the ingredients in LUPKYNIS?

Active ingredient: voclosporin

Inactive ingredients: alcohol, Vitamin E polyethylene glycol succinate, polysorbate 40, medium-chain triglycerides, gelatin

Manufactured for: Aurinia Pharmaceuticals Inc., Victoria, BC V8Z 7X8 Canada

Distributed by: Aurinia Pharma U.S., Inc., Rockville, MD 20850 USA

For more information, go to www.LUPKYNIS.com or call 1-833-AURINIA

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

Issued: 01/2021

FPI-0010

Reference ID: 4735432