Lupkynis® (voclosporin) capsules 7.9 mg

# LUPKYNIS EXPERIENCE PROGRAM OVERVIEW

A GUIDE FOR HEALTHCARE PROFESSIONALS

## INDICATION

LUPKYNIS is indicated in combination with a background immunosuppressive therapy regimen for the treatment of adult patients with active lupus nephritis (LN).

***Limitations of Use:*** Safety and efficacy of LUPKYNIS have not been established in combination with cyclophosphamide. Use of LUPKYNIS is not recommended in this situation.

## IMPORTANT SAFETY INFORMATION

**BOXED WARNINGS: MALIGNANCIES AND SERIOUS INFECTIONS**

**Increased risk for developing malignancies and serious infections with LUPKYNIS or other immunosuppressants that may lead to hospitalization or death.**

**Please see additional Important Safety Information throughout and full Prescribing Information including Boxed Warning and Medication Guide for LUPKYNIS at LUPKYNISpro.com.**

# Setting Expectations

## Help Your Patients Understand Why They're Being Prescribed LUPKYNIS

**Your patients may have questions before starting treatment. Here are some suggested talking points to help explain why you are prescribing them LUPKYNIS.**

### What's the goal of treatment?

- It's important to stop lupus nephritis' attack on the kidneys and help protect them from further irreversible damage. If left untreated, lupus nephritis can lead to kidney failure, which may require dialysis or a kidney transplant[1,2]

### What are the potential benefits of LUPKYNIS?

In clinical trials, LUPKYNIS[a] was shown to:

- **Help control lupus nephritis:** For people taking LUPKYNIS, the chance of getting their lupus nephritis under control[b] after 1 year of treatment was almost 3 times greater[c] than for people only taking mycophenolate mofetil (MMF) and steroids[3]
- **Work with low-dose steroids:** LUPKYNIS helped to stop the attack of lupus nephritis with low-dose steroids[3]
- **Rapidly reduce protein in urine:** People taking LUPKYNIS saw a 50% reduction of protein in the urine, on average after just 1 month[4]
- **Preserve kidney function:** People taking LUPKYNIS maintained stable kidney function for a total of 3 years[5,d]
  - Monitor eGFR regularly during treatment, and consider dose reduction or discontinuation in patients with decreases in eGFR from baseline[3]

Lowering proteinuria is a key measure of positive long-term renal outcomes for LN treatment.[6,7]

[a]As part of a treatment plan that included MMF and steroids.[3]
[b]Control was defined as reducing protein in the urine to ≤0.5 mg/mg, while helping maintain kidney function.[3]
[c]The odds ratio was 2.7. The odds ratio was determined by comparing the likelihood that someone taking LUPKYNIS along with MMF and steroids would get their lupus nephritis under control after 1 year of treatment to the likelihood for someone only taking MMF and steroids.[3,8]
[d]AURORA 2 was a double-blind, placebo-controlled, 24-month continuation study that enrolled 216 (84.6%) patients who completed 12 months of treatment in AURORA 1; 116 (64.8%) patients were enrolled in the LUPKYNIS arm, and 100 (56.2%) patients were enrolled in the active-control arm. Stable eGFR over 2-year extension period (annualized slope in the LUPKYNIS arm was -0.2 mL/min/1.73 $m^2$ vs. -5.4 mL/min/1.73 $m^2$ with active control). This is a post hoc analysis and should be interpreted with caution.[3,5]

eGFR=estimated glomerular filtration rate; LN=lupus nephritis; MMF=mycophenolate mofetil.

## IMPORTANT SAFETY INFORMATION (cont.)

**CONTRAINDICATIONS:** LUPKYNIS is contraindicated in patients taking strong CYP3A4 inhibitors because of the increased risk of acute and/or chronic nephrotoxicity, and in patients who have had a serious/severe hypersensitivity reaction to LUPKYNIS or its excipients.

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# As With Any Treatment, There May Be Tolerability Concerns When Taking LUPKYNIS[3]

## Common tolerability concerns include:[3,a]

- Decrease in eGFR
- High blood pressure
- Diarrhea
- Headache
- Cough
- Urinary tract infection
- Stomach pain
- Heartburn
- Loss of hair (alopecia)

In clinical trials, these side effects were well tolerated in the majority of patients.[4,5]

[a]During lupus nephritis clinical trials with LUPKYNIS, common side effects were reported as mild to moderate in most patients and usually did not result in having to stop taking LUPKYNIS.[4,5]

**There was a small, expected, early decrease in mean eGFR in the first 4 weeks of treatment with LUPKYNIS consistent with the known hemodynamic effects of CNIs.[4,5]**

To better prepare patients for your appointments, encourage them to use the personal tracker at the end of their patient brochure where they can log medications, proteinuria levels, and any symptoms they may experience.

## IMPORTANT SAFETY INFORMATION (cont.)

### WARNINGS AND PRECAUTIONS

**Lymphoma and Other Malignancies:** Immunosuppressants, including LUPKYNIS, increase the risk of developing lymphomas and other malignancies, particularly of the skin. The risk appears to be related to increasing doses and duration of immunosuppression rather than to the use of any specific agent.

**Serious Infections:** Immunosuppressants, including LUPKYNIS, increase the risk of developing bacterial, viral, fungal, and protozoal infections, including opportunistic infections which lead to serious, including fatal outcomes.

**Nephrotoxicity:** LUPKYNIS, like other calcineurin inhibitors (CNIs), may cause acute and/or chronic nephrotoxicity. The risk is increased when CNIs are concomitantly administered with drugs associated with nephrotoxicity. Monitor eGFR regularly.

**Hypertension:** Hypertension is a common adverse reaction of LUPKYNIS therapy and may require antihypertensive therapy. Monitor blood pressure regularly.

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# LUPKYNIS Oral Dosing Fits Into Your Patient's Day

**The Recommended Starting Dose of LUPKYNIS is 23.7 mg, Taken Twice Daily[3]**


**12-hour schedule**
Taken as close as possible to schedule[3]

**Empty stomach**
1 hour before or 2 hours after a meal[3]

**Swallow whole**
Should not open, crush, or divide capsules[3]

- LUPKYNIS is indicated in combination with MMF + steroids for the treatment of adult patients with active LN[3]
- Dose should be taken within 4 hours. Beyond 4 hours, wait until next scheduled dose; do not double the dose[3]

# Individualized eGFR-Based Dose Modifications

## Assess eGFR Every 2 Weeks for the First Month, Every 4 Weeks Through the First Year, and Quarterly Thereafter[3]

**eGFR ≥60 mL/min/1.73 m²**


No dose adjustment necessary; continue 3 capsules BID

**eGFR <60 mL/min/1.73 m²**

**≤20% reduction from baseline**

No dose adjustment necessary; continue 3 capsules BID

**>20% and <30% reduction from baseline**

Reduce dose to 2 capsules BID

Reassess eGFR within 2 weeks; if still >20% reduced from baseline, reduce dose to 1 capsule BID

Reassess eGFR within 2 weeks; if still >80% of baseline, consider increasing dose by 1 capsule BID; do not exceed starting dose

**≥30% reduction from baseline**

Discontinue LUPKYNIS

Reassess eGFR within 2 weeks; if >80% of baseline, consider restarting at 1 capsule BID

BID=twice daily dosage; eGFR=estimated glomerular filtration rate; LN=lupus nephritis; MMF=mycophenolate mofetil; PO=per os (orally).

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# Electronically Prescribing LUPKYNIS

## Aurinia Alliance® supports LUPKYNIS patients and the offices that prescribe LUPKYNIS throughout the prescription journey

1. **Prescribe LUPKYNIS to PharmaCord Pharmacy**
   - If you can't find LUPKYNIS, you may search "voclosporin"
   - PharmaCord Pharmacy, 11001 Bluegrass Parkway, Suite 200, Louisville, KY 40299. It may be found under mail-order pharmacies, NPI 1699202838
2. **Include ICD.10 code or diagnosis**
3. **Enter dosage and refills:**
   - LUPKYNIS is available in 7.9 mg capsules
   - Recommended starting dose is 3 capsules BID. Please see Prescribing Information for guidance on potential dosing adjustments

**23.7 mg (7.9 mg/capsule) PO BID x 30 days # 180 capsules refills**

NDC 75626-001-02: Carton containing 180 capsules (3 wallets)

**15.8 mg (7.9 mg/capsule) PO BID x 30 days # 120 capsules refills**

**7.9 mg (7.9 mg/capsule) PO BID x 30 days # 60 capsules refills**

NDC 75626-001-01: Wallet containing 60 capsules

## IMPORTANT SAFETY INFORMATION (cont.)

### WARNINGS AND PRECAUTIONS

**Neurotoxicity:** LUPKYNIS, like other CNIs, may cause a spectrum of neurotoxicities: severe include posterior reversible encephalopathy syndrome (PRES), delirium, seizure, and coma; others include tremor, paresthesia, headache, and changes in mental status and/or motor and sensory functions. Monitor for neurologic symptoms.

**Hyperkalemia:** Hyperkalemia, which may be serious and require treatment, has been reported with CNIs, including LUPKYNIS. Concomitant use of agents associated with hyperkalemia may increase the risk for hyperkalemia. Monitor serum potassium levels periodically.

**QTc Prolongation:** LUPKYNIS prolongs the QTc interval in a dose-dependent manner when dosed higher than the recommended lupus nephritis therapeutic dose. The use of LUPKYNIS in combination with other drugs that are known to prolong QTc may result in clinically significant QT prolongation.

**Immunizations:** Avoid the use of live attenuated vaccines during treatment with LUPKYNIS. Inactivated vaccines noted to be safe for administration may not be sufficiently immunogenic during treatment with LUPKYNIS.

**Pure Red Cell Aplasia:** Cases of pure red cell aplasia (PRCA) have been reported in patients treated with another CNI immunosuppressant. If PRCA is diagnosed, consider discontinuation of LUPKYNIS.

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# Setting Expectations for a Successful Start

**You have decided LUPKYNIS may be right for your patients. Aurinia Alliance® is designed to set them up for a successful start to treatment and access.**

**When starting your patient on LUPKYNIS, Aurinia Alliance understands that each treatment journey is unique and offers:**

- **$0 co-pay for eligible patients**
- **Education materials**
- **Help with understanding** insurance and funding options
- **A specialty pharmacy** that will deliver LUPKYNIS directly to patients

Your patient team includes **one-on-one support from a dedicated Nurse Case Manager.** Bilingual Nurse Case Managers are also available to support your Spanish-speaking patients.

**Aurinia Alliance is a program that provides personalized support through lupus nephritis education, tools, and resources.**

Aurinia Alliance®

**Visit AuriniaAlliance.com** to learn more about Aurinia Alliance for your patients

## IMPORTANT SAFETY INFORMATION (cont.)

### WARNINGS AND PRECAUTIONS

**Drug-Drug Interactions:** Avoid co-administration of LUPKYNIS and strong CYP3A4 inhibitors or with strong or moderate CYP3A4 inducers. Co-administration of LUPKYNIS with strong CYP3A4 inhibitors is contraindicated. Reduce LUPKYNIS dosage when co-administered with moderate CYP3A4 inhibitors. Avoid use of LUPKYNIS with strong or moderate CYP3A4 inducers.

### ADVERSE REACTIONS

The most common adverse reactions (≥3%) were glomerular filtration rate decreased, hypertension, diarrhea, headache, anemia, cough, urinary tract infection, abdominal pain upper, dyspepsia, alopecia, renal impairment, abdominal pain, mouth ulceration, fatigue, tremor, acute kidney injury, and decreased appetite.

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# Get Started With LUPKYNIS and Aurinia Alliance®

## Aurinia Alliance Provides a Dedicated Support Team for Your Patients and Your Office

**Patient Start Form is submitted via fax or through eRX**

Be sure to complete all applicable fields on the patient start form to assist with prior authorization

Have patients consent to **Aurinia Alliance** (*see page 6*)

**Nurse Case Manager**

provides personalized support of your patients throughout their treatment

**Our Specialty Pharmacy**

partners will apply co-pay savings and ship directly to your patients

**IMPORTANT SAFETY INFORMATION (cont.)**

**SPECIFIC POPULATIONS**

**Pregnancy: Avoid use of LUPKYNIS.**

**Lactation:** Consider the mother's clinical need of LUPKYNIS and any potential adverse effects to the breastfed infant when prescribing LUPKYNIS to a lactating woman.

**Renal Impairment:** LUPKYNIS is not recommended in patients with baseline eGFR ≤45 mL/min/1.73 $m^2$ unless benefit exceeds risk. If used in this population, reduce LUPKYNIS dose.

**Hepatic Impairment:** For mild or moderate hepatic impairment, reduce LUPKYNIS dose. Avoid use with severe hepatic impairment.

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# Goals for Treatment

## 2024 ACR Guideline for the Treatment and Management of LN Recommends:[1]

First-line therapy options include a CNI (e.g., LUPKYNIS) as part of a preferred triple immunosuppressive therapy regimen with steroids and MPAA (e.g., MMF) in adults with active (newly diagnosed or flare) class III or IV (±V) or class V LN

Continue treatment to achieve complete renal response

- Proteinuria of ≤0.5 g/g within 6-12 months
- Stabilization or improvement of kidney function (±20% of baseline)

Monitor frequently to quantify proteinuria, at least every 3 months in people with no complete renal response and at least every 3-6 months in people who have achieved a complete renal response

Taper oral glucocorticoid to ≤5 mg/day by 6 months

If complete renal response achieved, continue same treatment regimen for a total duration of therapy ≥3-5 years

ACR=American College of Rheumatology; CNI=calcineurin inhibitor; LN=lupus nephritis; MMF=mycophenolate mofetil; MPAA=mycophenolic acid analogs.

**References: 1.** 2024 American College of Rheumatology (ACR) guideline for the screening, treatment, and management of lupus nephritis: guideline summary. *American College of Rheumatology.* November 15, 2024. **2.** Anders H-J, et al. *Nat Rev Dis Primers.* 2020;6(1):7. **3.** Lupkynis. Prescribing information. Aurinia Pharma U.S., Inc; 2024. **4.** Rovin BH, et al. *Lancet.* 2021;397(10289):2070-2080. **5.** Saxena A, et al. *Arthritis Rheumatol.* 2024;76(1):59-67. **6.** Chen YE, et al; Collaborative Study Group. *Clin J Am Soc Nephrol.* 2008;3(1):46-53. **7.** Houssiau FA, et al. *Arthritis Rheum.* 2004;50(12):3934-3940. **8.** Aurinia Pharma U.S., Inc. Data on file.

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