In the treatment of adult patients with active lupus nephritis...

START WITH A STRONG FIRST LINE

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Indications

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.

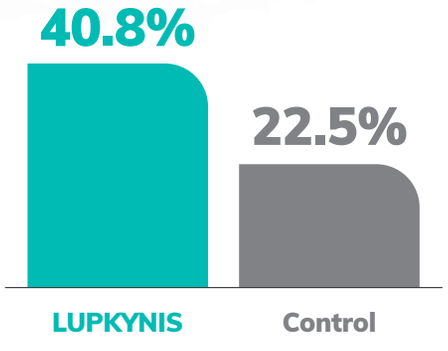
Please see additional Important Safety Information and accompanying Prescribing Information including Boxed Warning and Medication Guide for LUPKYNIS.

Lupkynis™ (voclosporin) capsules 7.9 mg

Using LUPKYNIS™ (voclosporin) in combination with MMF and low-dose steroids can transform your first-line lupus nephritis regimen[1,2,a]

Greater Complete Renal Response[b]

Significantly greater complete renal response rate with LUPKYNIS at Week 52 (P<0.001)



- Improvements in complete renal response were also seen at Week 24[1,c]

Substantial Proteinuria Reductions[c]

Median time to UPCR ≤0.5 mg/mg[1,2,d]:

(HR: 2.0; 95% CI: 1.5, 2.7)

Median time to 50% UPCR reduction[2]:

(HR: 2.1; 95% CI: 1.6, 2.6)

Low Steroid Use[e]

Demonstrated efficacy with a low-dose steroid regimen

≤2.5 mg/day by Week 16

Consistent efficacy observed across racial and ethnic subgroups[3,f] and biopsy class[4,g]

[a]The AURORA Phase 3 trial was a randomized, double-blind, placebo-controlled trial of LUPKYNIS 23.7 mg BID in combination with MMF (target 2 g/day) and corticosteroids (n=179) vs placebo BID in combination with MMF and corticosteroids (n=178) in adults with class III or IV (alone or in combination with class V) or class V lupus nephritis. Efficacy was established on the basis of complete renal response at Week 52. Key secondary endpoints included complete renal response at Week 24, partial renal response (50% reduction in UPCR from baseline) at Weeks 24 and 52, time to UPCR ≤0.5 mg/mg, and time to 50% reduction in UPCR.[1,4]

[b]The primary efficacy endpoint of complete renal response was defined as a confirmed UPCR of ≤0.5 mg/mg; eGFR ≥60 mL/min/1.73 m^2 or no confirmed decrease from baseline in eGFR of >20% or no treatment- or disease-related eGFR-associated event at time of assessment; presence of sustained, low-dose steroids (≤10 mg prednisone from Weeks 44-52); and no administration of rescue medications. Proteinuria reduction was based on time to UPCR of ≤0.5 mg/mg.[1]

[c]Secondary endpoint in the AURORA Phase 3 trial.

[d]All patients were followed for 4 weeks after the last visit at Week 52.[2]

[e]Study included scheduled steroid taper from 20-25 mg/day at Week 1 to 2.5 mg/day by Week 16. Approximately 80% of patients in both treatment arms were able to achieve a steroid taper to ≤2.5 mg/day by Week 16.[1]

[f]Post hoc analysis; the study was not powered to detect differences in the treatment effect between these subgroups; therefore, results from this post hoc analysis should be interpreted with caution.

[g]Results were not statistically significant for class V. However, the odds ratios favored LUPKYNIS over control (class V [OR: 2.7; 95% CI: 0.8, 9.7]; other class [OR: 2.6; 95% CI: 1.6, 4.4]).[2,4]

BID=twice daily; eGFR=estimated glomerular filtration rate; HR=hazard ratio; MMF=mycophenolate mofetil; OR=odds ratio; UPCR=urine protein/creatinine ratio.

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Aurinia Alliance™

Dedicated Support, Personalized For You

Dedicated to providing support and resources personalized to meet the needs of your patients and your practice

Educational resources

Reliable, patient-friendly information about lupus nephritis to help increase patient knowledge of their disease

Financial assistance

Help navigating access to Aurinia medication, including:

- Benefit investigation and verification
- Prior authorizations, appeals, and resources
- Financial assistance options

Aurinia treatment support

Dedicated one-on-one support from a Nurse Case Manager to help your patients stay organized, informed, and on track with their prescribed Aurinia treatment

Questions? Call **1-833-AURINIA (1-833-287-4642)** 8AM to 8PM ET, fax to **1-833-213-1001**, email **support@AuriniaAlliance.com,** or visit **LUPKYNISpro.com/starting-patients/**

Visit LUPKYNISpro.com for more information

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.

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 may 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.

Hypertension: Hypertension is a common adverse reaction of LUPKYNIS therapy and may require antihypertensive therapy.

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.

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.

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.

Drug-Drug Interactions: Avoid co-administration of LUPKYNIS and strong CYP3A4 inhibitors or with strong or moderate CYP3A4 inducers. Reduce LUPKYNIS dosage when co-administered with moderate CYP3A4 inhibitors. Reduce dosage of certain P-gp substrates with narrow therapeutic windows when co-administered.

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.

SPECIFIC POPULATIONS

Pregnancy/Lactation: May cause fetal harm. Advise not to breastfeed.

Renal Impairment: 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.

Please see accompanying Prescribing Information including Boxed Warning and Medication Guide for LUPKYNIS.

References: 1. LUPKYNIS [package insert]. Rockville, MD: Aurinia Pharma U.S., Inc., 2021. **2.** Aurinia Pharma U.S., Inc. Data on file. **3.** Arriens C, Polyakova S, Adzerikho I, et al; AURORA Study Group. AURORA phase 3 study demonstrates voclosporin statistical superiority over standard of care in lupus nephritis. Presented at: EULAR European E-Congress of Rheumatology 2020; June 3-Sept 1, 2020. **4.** Gibson K, Parikh S, Saxena A, et al; AURORA Study Group. AURORA phase 3 study demonstrates voclosporin statistical superiority over standard of care in lupus nephritis. Presented at: National Kidney Foundation virtual 2020 Spring Clinical Meetings; March 26-29, 2020.

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