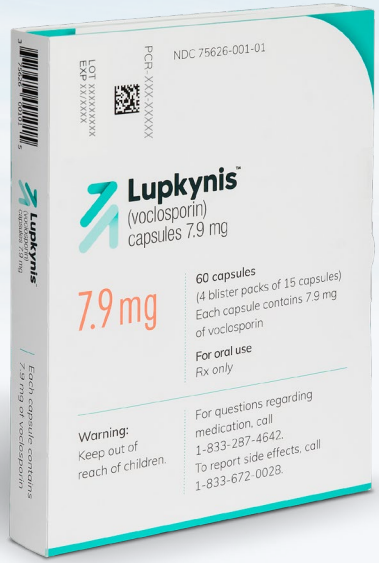
Dosing that fits your patient's life

No drug level monitoring

Lupkynis™ (voclosporin) capsules 7.9 mg



Recommendations for dosing and administration of LUPKYNIS™[1a]

Starting dose 23.7 mg BID

3 capsules (7.9 mg each) BID

12-hour schedule

Taken as close as possible to schedule[b]

Empty stomach

1 hour before or 2 hours after meal

Swallow whole

Should not open, crush, or divide capsules

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

BID=twice daily; LN=lupus nephritis; MMF=mycophenolate mofetil.

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.

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.

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

Dosing recommendations for specific patients[1]

Renal impairment

- Not recommended in patients with baseline eGFR ≤45 mL/min/1.73 m^2 unless benefit exceeds risk
- If used in patients with severe renal impairment, reduce LUPKYNIS dose

Hepatic impairment

- In patients with mild or moderate hepatic impairment, reduce LUPKYNIS dose
- Avoid use in patients with severe hepatic impairment

Hypertension (BP >165/105 mmHg) or with hypertensive emergency

- Discontinue LUPKYNIS and initiate antihypertensive therapy

Drug interactions with moderate CYP3A4 inhibitors[a]

- In patients taking moderate CYP3A4 inhibitors, reduce LUPKYNIS dose
- Do not use with strong inhibitors of CYP3A4
- Avoid foods and drinks containing grapefruit

For a full list of dosing recommendations, please see the Prescribing Information for LUPKYNIS.

[a]Moderate CYP3A4 inhibitors include verapamil, fluconazole, and diltiazem. Strong CYP3A4 inhibitors include ketoconazole, itraconazole, and clarithromycin.

BP=blood pressure; CYP=cytochrome P450; eGFR=estimated glomerular filtration rate.

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.

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

Lupkynis™ (voclosporin) capsules 7.9 mg

Navigating a rare disease can be complex—Aurinia Alliance™ can help

Get Started With LUPKYNIS™

Important Safety Information (cont.)

WARNINGS AND PRECAUTIONS

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.

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

Lupkynis™ (voclosporin) capsules 7.9 mg

Individualized eGFR-based dose modifications[1a]

Assess eGFR every 2 weeks for the first month, and every 4 weeks thereafter, and adjust dose as necessary

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 ≥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

[a]The phase 3 study was designed to allow for dose modifications due to eGFR reductions.

Important Safety Information (cont.)

SPECIFIC POPULATIONS

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

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

Reference: 1. LUPKYNIS. Package insert. Aurinia Pharma U.S., Inc.; 2021.

Aurinia™

Lupkynis™ (voclosporin) capsules 7.9 mg