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# Voclosporin

**Also called:** Lupkynis; ISA247; VCS

## What it is

A cyclosporine analogue approved as Lupkynis (2021) for active lupus nephritis in adults, in combination with background immunosuppression.

## Approval status

**FDA Approved.** Approved in the US as Lupkynis (Aurinia Pharmaceuticals), NDA 213716, on January 22, 2021, in combination with a background immunosuppressive regimen for adults with active lupus nephritis (Drugs@FDA via openFDA and the Lupkynis label, read October 3, 2026).

## Dosing, as printed in the page's Recommended Dosing box

### Manufacturer's recommended dosing (FDA label)

From the prescribing information. Other doses studied, if any, are in the full dosing data below.

| Protocol and source | Dose | Frequency | Duration | Route |
|---|---|---|---|---|
| Label: lupus nephritis **[Approved label]** Lupkynis prescribing information, section 2 (DailyMed set 9f489295, effective August 25, 2026) | 23.7 mg (three 7.9 mg capsules) | Twice daily, about 12 hours apart, on an empty stomach | Ongoing, reassessed | Oral |

### Used in human trials

No manufacturer dose exists for this use: these are amounts given in published trials, not recommendations.

| Protocol and source | Dose | Frequency | Duration | Route |
|---|---|---|---|---|
| AURORA 1 (2021) **[Human study]** PMID 33971155 | 23.7 mg | Twice daily | 52 weeks | Oral |

Educational information, not medical advice. Each dose above is tagged with its source: an approved label, a published human study, animal data, or amounts reported by users. None is a recommendation for you. An unapproved compound has no established safe or effective human dose, and products sold for "research use only" are not made or tested for people. Talk to a doctor before acting on anything on this site, including before you start, stop or change any medicine or dose.

## Key human evidence

The first 3 of the 9 human studies carded on the page (12 study cards in all):

• **AURORA 1: phase 3 in lupus nephritis** (Human, 2021). In 357 patients, complete renal response at week 52 was reached by 41% on voclosporin against 23% on placebo (odds ratio 2.65), both with mycophenolate and steroids; serious adverse events occurred in 21% of each group. **PMID 33971155**

• **AURA-LV: phase 2** (Human, 2019). In 265 patients, complete remission at 24 weeks was 32.6% on low-dose and 27.3% on high-dose voclosporin against 19.3% on placebo; there were more serious adverse events on voclosporin and more deaths in the low-dose group (11.2%, against 1.1% on placebo). **PMID 30420324**

• **AURORA 2: two more years** (Human, 2024). In 216 patients continuing treatment, 86.1% completed the study with no unexpected safety signals; decreased kidney function and high blood pressure were reported more often on voclosporin, but mean eGFR stayed in the normal range and stable. **PMID 37466424**

## Interactions

From the FDA label's drug-interaction section (Aurinia. LUPKYNIS (voclosporin) US prescribing information, section 7. DailyMed version of August 25, 2026, read October 3, 2026):

• With strong CYP3A4 inhibitors (ketoconazole, itraconazole, clarithromycin): contraindicated: raise voclosporin exposure (FDA label)
• With moderate CYP3A4 inhibitors (verapamil, fluconazole, diltiazem): reduce the voclosporin dose as the label specifies (FDA label)
• With grapefruit: avoid food or drink containing grapefruit (FDA label)
• With strong and moderate CYP3A4 inducers: avoid: lower voclosporin exposure and may reduce efficacy (FDA label)
• With narrow-therapeutic-window P-gp substrates: voclosporin inhibits P-gp; reduce the substrate's dose if needed (FDA label)
• With OATP1B1/1B3 substrates (e.g. simvastatin): voclosporin inhibits these transporters and can raise substrate exposure (FDA label)

## Side effects and cautions

| Reported side effects | Contraindications and cautions |
|---|---|
| • Decreased kidney filtration and high blood pressure<br>• Infections, including pneumonia, in the lupus trials<br>• Infections in 62.2% against 54.9% in pooled lupus trials, mostly mild to moderate<br>• Gastrointestinal effects in 45.3% against 35.3%<br>• Decreased kidney filtration and high blood pressure, the reasons the label requires regular eGFR and blood-pressure checks | • Boxed warning: cancers, including lymphoma, and serious infections<br>• Kidney toxicity, high blood pressure and nerve toxicity<br>• High potassium, QT prolongation and pure red cell aplasia<br>• Strong CYP3A4 inhibitors; avoid grapefruit |

## Five questions to ask

1. Is Voclosporin right for me, and is the labelled dose on this sheet right for my weight, age, kidney and liver function?
2. Here are the medicines and supplements I take. Do any of them interact with Voclosporin? This sheet lists the interactions on record.
3. Which side effects should make me stop and call you, for example decreased kidney filtration and high blood pressure?
4. Do any of the cautions on this sheet apply to me, such as: Boxed warning: cancers, including lymphoma, and serious infections?
5. What should we check before I start and while I am on it (blood tests, blood pressure, weight), and how often?

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