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Lesinurad Dosage

Applies to the following strengths: 200 mg

Usual Adult Dose for:

- [Gout](#)

Additional dosage information:

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Usual Adult Dose for Gout

200 mg orally once a day

Maximum dose: 200 mg per day

Comments:

- Coadminister with a xanthine oxidase inhibitor (e.g., allopurinol or febuxostat); if coadministered with allopurinol, total daily allopurinol doses should not be less than 300 mg (or less than 200 mg with CrCl less than 60 mL/min).
- If xanthine oxidase inhibitor is interrupted, this drug should also be interrupted.
- This drug should not be used to treat asymptomatic hyperuricemia.

Use: Add-on treatment for hyperuricemia associated with gout in patients with elevated serum uric acid despite treatment with a xanthine oxidase inhibitor

Renal Dose Adjustments

CrCl 45 mL/min or greater: No adjustment recommended.

CrCl less than 45 mL/min: Not recommended

CrCl less than 30 mL/min: Contraindicated

- For serum creatinine levels greater than 2 times pretreatment level: Interrupt therapy; do not restart without another explanation for serum creatinine abnormalities.
- If CrCl becomes persistently less than 45 mL/min during therapy, therapy should be discontinued.

Liver Dose Adjustments

Mild to moderate liver impairment (Child-Pugh A to B): No adjustment recommended.

Severe liver impairment (Child-Pugh C): Not recommended.

Precautions

US BOXED WARNING:

- **ACUTE RENAL FAILURE:** Increased frequency of acute renal failure observed when this drug was given as monotherapy. This drug should be used in combination with a xanthine oxidase inhibitor.

Safety and efficacy have not been established in patients younger than 18 years.

Consult WARNINGS section for additional precautions.

Dialysis

Contraindicated

Other Comments

Administration advice:

- Take orally once a day in the morning with food and water
- Take morning dose at same time as morning dose of xanthine oxidase inhibitor (XOI)
- Patients should stay well hydrated (e.g., 2 liters of liquid per day)
- If a dose is missed, skip the missed dose; do not double the dose.
- If XOI treatment is stopped, this drug should be stopped.

Storage requirements:

- Protect from light

General:

- This drug should not be used to treat asymptomatic hyperuricemia or as monotherapy.

- Gout flares may occur due to increased urate mobilization from tissue deposits, especially during initiation; gout flare prophylaxis is recommended according to practice guidelines.
- If gout flares occur during treatment, manage concurrently; discontinuation of this drug should not be necessary.
- This drug is not expected to be effective in patients with severe renal impairment, end stage renal disease, or on dialysis.

Monitoring:

- Serum creatinine levels should be obtained at baseline and periodically during treatment; in patients with CrCl of 45 to less than 60 mL/min or serum creatinine 1.5 to 2 times pretreatment levels, more frequent monitoring is advised.
- Serum creatinine should be promptly assessed in patients reporting signs/symptoms of acute uric acid nephropathy (e.g., acute flank pain, nausea, vomiting).

Patient advice:

- Instruct patients to keep well hydrated while using this drug (e.g., 2 L fluid per day).
- Inform patients that gout flares may occur, and they should not stop taking this drug if a gout flare occurs.
- Patients should be instructed to report signs/symptoms of acute nephropathy to health care provider.
- Patients should be advised to speak to healthcare provider if pregnant, intend to become pregnant, or are breastfeeding; patients using hormonal contraception to prevent pregnancy will need to speak with their health care provider about using a non-hormonal back-up method of birth control during therapy.

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Patient resources

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- [Gout](#)


Further information

Always consult your healthcare provider to ensure the information displayed on this page applies to your personal circumstances.


[Medical Disclaimer](#)

DRUG STATUS

 **Availability**
Discontinued

 **Pregnancy & Lactation**
Risk data available

CSA Schedule*
N/A Not a controlled drug

 **Approval History**
Drug history at FDA



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