# Prinivil (lisinopril) - Drug Summary

Merck Sharp & Dohme Corp.





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Prinivil
(lisinopril)

## BOXED WARNING

D/C when pregnancy is detected. Drugs that act directly on the renin-angiotensin system (RAS) can cause injury and death to the developing fetus.

## THERAPEUTIC CLASS

ACE inhibitor

## DEA CLASS

RX

## ADULT DOSAGE & INDICATIONS

### Hypertension

**Initial:** 10mg qd or 5mg qd in patients taking diuretics
**Usual Range:** 20-40mg qd. Doses up to 80mg have been used but do not appear to give a greater effect

May add a low-dose diuretic (eg, hydrochlorothiazide 12.5mg) if BP is not controlled

### Heart Failure

**Reduce Signs/Symptoms in Patients Not Responding Adequately to Diuretics and Digitalis:**
**Adjunct w/ Diuretics and (Usually) Digitalis:**
**Initial:** 5mg qd; 2.5mg qd w/ hyponatremia (serum $Na^+$ <130mEq/L)
**Max:** 40mg qd

Diuretic dose may need to be adjusted to help minimize hypovolemia

### Acute Myocardial Infarction

**Reduction of Mortality in Treatment of Hemodynamically Stable Patients w/in 24 Hrs of Acute MI (AMI):** 5mg w/in 24 hrs of onset of symptoms, followed by 5mg after 24 hrs, 10mg after 48 hrs, and then 10mg qd for at least 6 weeks

In patients w/ low systolic BP (SBP) (100-120mmHg) during the first 3 days after infarct, initiate therapy w/ 2.5mg. If hypotension occurs (SBP ≤100mmHg) consider doses of 2.5mg or 5mg. D/C therapy if prolonged hypotension occurs (SBP <90mmHg for >1 hr)

## PEDIATRIC DOSAGE & INDICATIONS

### Hypertension

**≥6 Years:**
**GFR >30mL/min/1.73m$^2$:**
**Initial:** 0.07mg/kg qd (up to 5mg total)
**Titrate:** Adjust dose according to BP response
**Max:** 0.61mg/kg (up to 40mg) qd

## DOSING CONSIDERATIONS

**Renal Impairment**
**CrCl 10-30mL/min:**
Reduce initial dose to 1/2 of the usual recommended dose (eg, HTN, 5mg; heart failure or AMI, 2.5mg)
**Hemodialysis or CrCl <10mL/min:**

**Initial:** 2.5mg qd

**Pediatric Patients:**
**GFR <30mL/min/1.73m$^2$:** Not recommended

## ADMINISTRATION

Oral route

## HOW SUPPLIED

**Tab:** 5mg*, 10mg*, 20mg* *scored

## CONTRAINDICATIONS

History of ACE inhibitor-associated angioedema or hypersensitivity, hereditary or idiopathic angioedema. Coadministration w/ aliskiren in patients w/ diabetes.

## WARNINGS/PRECAUTIONS

Head/neck angioedema reported; d/c and administer appropriate therapy. Patients w/ a history of angioedema unrelated to ACE inhibitor therapy may be at increased risk of angioedema during therapy. Higher rate of angioedema in blacks than nonblacks. Intestinal angioedema reported; monitor for abdominal pain. Anaphylactoid reactions reported during desensitization w/ hymenoptera venom, dialysis w/ high-flux membranes, and LDL apheresis w/ dextran sulfate absorption. May cause changes in renal function, including acute renal failure, especially in patients whose renal function may depend in part on the activity of the RAS; consider withholding or discontinuing therapy if a clinically significant decrease in renal function develops. May cause symptomatic hypotension, sometimes complicated by oliguria, progressive azotemia, acute renal failure, or death; closely monitor patients at risk of excessive hypotension for the first 2 weeks of treatment and whenever therapy and/or diuretic dose is increased. Avoid in patients who are hemodynamically unstable after an AMI. Symptomatic hypotension may occur in patients w/ severe aortic stenosis or hypertrophic cardiomyopathy. Hypotension may occur w/ major surgery or during anesthesia. May cause hyperkalemia; periodically monitor serum $K^+$ during therapy. Associated w/ a syndrome that starts w/ cholestatic jaundice or hepatitis and progresses to fulminant hepatic necrosis and sometimes death; d/c therapy if jaundice or marked hepatic enzyme elevations develop.

## ADVERSE REACTIONS

Headache, dizziness, cough, hypotension, chest pain, increased creatinine, hyperkalemia, syncope.

## DRUG INTERACTIONS

See Contraindications. Initiation of therapy in patients on diuretics may result in excessive reduction of BP. Decrease or d/c diuretic or increase the salt intake prior to initiation of therapy; if this is not possible, reduce the starting dose of lisinopril. Attenuates $K^+$ loss caused by thiazide-type diuretics. $K^+$-sparing diuretics (eg, spironolactone, amiloride, triamterene) may increase hyperkalemia risk; frequently monitor serum $K^+$ if concomitant use of such agents is indicated. Increased risk of hyperkalemia w/ $K^+$ supplements or $K^+$-containing salt substitutes. May cause an increased blood-glucose-lowering effect w/ risk of hypoglycemia w/ antidiabetic medicines (insulins, oral hypoglycemic agents). NSAIDs, including selective COX-2 inhibitors, may result in deterioration of renal function, including possible acute renal failure in elderly, volume depleted or patients w/ compromised renal function. Antihypertensive effect may be attenuated by NSAIDs. Dual blockade of the RAS is associated w/ increased risks of hypotension, syncope, hyperkalemia, and changes in renal function (including acute renal failure); avoid combined use of RAS inhibitors, and monitor BP, renal function, and electrolytes w/ other agents that affect the RAS. Avoid w/ aliskiren in patients w/ renal impairment (GFR <60mL/min). Lithium toxicity reported; monitor serum lithium levels during concurrent use. Nitritoid reactions reported w/ injectable gold. Increased BUN and SrCr w/ diuretics. Coadministration w/ mTOR inhibitors (eg, temsirolimus, sirolimus, everolimus) may increase risk for angioedema.

## PREGNANCY AND LACTATION

**Pregnancy:** Category D.
**Lactation:** Not for use in nursing.

## MECHANISM OF ACTION

ACE inhibitor; decreases plasma angiotensin II, which leads to decreased vasopressor activity and decreased aldosterone secretion.

## PHARMACOKINETICS

**Absorption:** $T_{max}$=7 hrs (adults), 6 hrs (pediatric patients). **Elimination:** Urine (unchanged); $T_{1/2}$=12 hrs.

## ASSESSMENT

Assess for hypersensitivity to the drug, hereditary or idiopathic angioedema, history of ACE inhibitor-associated angioedema, risk factors for hyperkalemia, risk of excessive hypotension, renal artery stenosis, severe aortic stenosis or hypertrophic cardiomyopathy, renal impairment, pregnancy/nursing status, and possible drug interactions.

## MONITORING

Monitor for angioedema, anaphylactoid reactions, hyperkalemia, and other adverse reactions. Monitor BP, LFTs, serum $K^+$, and renal function.

## PATIENT COUNSELING

Inform of pregnancy risks and discuss treatment options for women planning to become pregnant; instruct to report pregnancy to physician as soon as possible. Instruct to immediately report signs/symptoms of

angioedema and to avoid drug until they have consulted w/ prescribing physician. Instruct to report lightheadedness, especially during 1st few days of therapy; if syncope occurs, advise to d/c therapy until physician is consulted. Advise that excessive perspiration, dehydration, and other causes of volume depletion (eg, vomiting, diarrhea) may lead to excessive fall in BP; instruct to consult w/ a physician. Advise not to use salt substitutes containing $K^+$ w/o consulting physician. Advise diabetic patients treated w/ oral antidiabetic agents or insulin to closely monitor for hypoglycemia, especially during the 1st month of combined use. Instruct to report promptly any indication of infection, which may be a sign of leukopenia/neutropenia.

## STORAGE

15-30°C (59-86°F). Protect from moisture.

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