

Arbli (losartan) – New drug approval

- On March 13, 2025, the [FDA approved](#) Scinture's [Arbli \(losartan\)](#) oral suspension, for the:
 - Treatment of hypertension in adults and pediatric patients 6 years of age and older, to lower blood pressure
 - Reduction of stroke risk in patients with hypertension and left ventricular hypertrophy, but there is evidence that this benefit does not apply to Black patients
 - Treatment of diabetic nephropathy with an elevated serum creatinine and proteinuria (urinary albumin to creatinine ratio ≥ 300 mg/g) in patients with type 2 diabetes and a history of hypertension.
- Losartan is an angiotensin II receptor blocker (ARB) that is also currently available generically as an oral tablet.
- Arbli carries a boxed warning for **fetal toxicity**.
- Arbli is contraindicated in:
 - Patients who are hypersensitive to any component of this product
 - For co-administration with aliskiren in patients with diabetes.
- Additional warnings and precautions for Arbli include hypotension in volume- or salt-depleted patients, renal function deterioration, and hyperkalemia.
- The most common adverse reactions ($\geq 2\%$ and greater than placebo) with Arbli use are dizziness, upper respiratory infection, nasal congestion, and back pain.
- The usual starting dose of Arbli for adult hypertension is 50 mg orally once daily. The dosage can be increased to a maximum dose of 100 mg orally once daily as needed to control blood pressure. A starting dose of 25 mg once daily is recommended for patients with possible intravascular depletion (eg, on diuretic therapy).
 - In pediatric patients with hypertension, the usual recommended starting dose is 0.7 mg per kg orally once daily (up to 50 mg total) administered as a suspension. Dosage should be adjusted according to blood pressure response. Doses above 1.4 mg per kg (or in excess of 100 mg) daily have not been studied in pediatric patients.
- The usual starting dose in hypertensive patients with left ventricular hypertrophy is 50 mg orally once daily. Hydrochlorothiazide 12.5 mg daily should be added and/or the dose of Arbli should be increased to 100 mg orally once daily followed by an increase in hydrochlorothiazide to 25 mg once daily based on blood pressure response.
- The usual starting dose in patients with nephropathy and type 2 diabetes is 50 mg orally once daily. The dose should be increased to 100 mg orally once daily based on blood pressure response.
- Scinture's launch plans for Arbli are pending. Arbli will be available as a 10 mg/mL oral suspension.